UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SECURITIES AND EXCHANGE COMMISSION, Plaintiff, v. BIOVAIL CORPORATION, EUGENE MELNYK, BRIAN CROMBIE, JOHN MISZUK, and KENNETH HOWLING, Defendants.	No. 08-cv-02979 (LAK) (GWG) ECF Case

DECLARATION OF SHAWN J. CHEN IN SUPPORT OF DEFENDANT BRIAN CROMBIE'S MOTION TO DISMISS THE AMENDED COMPLAINT UNDER FED. R. CIV. P. 9(b)

I, Shawn J. Chen, declare the following to be true under penalty of perjury:

1. I am a member of the Bar of this Court and a partner of Cleary Gottlieb Steen & Hamilton LLP, attorneys for Defendant Brian Crombie. I submit this declaration in support of Defendant Brian Crombie's Motion to Dismiss the Amended Complaint under Fed. R. Civ. P. 9(b).
2. Attached hereto as Exhibit A is a true and correct copy of the Securities and Exchange Commission's amended complaint filed on July 31, 2008.
3. Attached hereto as Exhibit B is a true and correct copy of the Product Development and Royalty Agreement between Biovail Laboratories, Inc. and Pharmaceutical Technologies Corporation.
4. Attached hereto as Exhibit C is a true and correct copy of the Letter from Ernst & Young LLP to Mr. Brian Crombie, dated June 29, 2001.

5. Attached hereto as Exhibit D is a true and correct copy of the Letter from Mr. Brian Crombie to Mr. Stan Hull, dated June 19, 2003.

6. Attached hereto as Exhibit E is a true and correct copy of the Approval Letter from Dr. Russell Katz, Director, Food and Drug Administration, to Mary E. Martinson.

Dated: August 22, 2008

Respectfully submitted,

s/Shawn J. Chen
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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SECURITIES AND EXCHANGE COMMISSION,	
Plaintiff,	
-against-	**08 Civ. 02979 (LAK)** **ECF CASE**
BIOVAIL CORPORATION, **EUGENE N. MELNYK,** **BRIAN CROMBIE,** **JOHN MISZUK, and** **KENNETH G. HOWLING,**	**AMENDED COMPLAINT**
Defendants.	

Plaintiff Securities and Exchange Commission, for its Amended Complaint against Defendants Biovail Corporation ("Biovail" or the "Company"), Eugene N. Melnyk, Brian Crombie, John Miszuk, and Kenneth G. Howling (collectively, "Defendants"), alleges as follows:

SUMMARY OF ALLEGATIONS

1. This case involves chronic fraudulent conduct – including financial reporting fraud and other intentional public misrepresentations – by Biovail Corporation, a Canadian pharmaceutical company whose common stock is traded on the New York and Toronto stock exchanges. Obsessed with meeting quarterly and annual earnings guidance, Biovail's executives repeatedly overstated earnings and hid losses in order to deceive investors and create the appearance of achieving that goal. And, when it ultimately became impossible to continue to conceal the Company's poor performance, Biovail actively misled investors and analysts as to its cause. This corrupt strategy was employed by Biovail's most senior officers: Eugene Melnyk, former chairman and chief executive officer; Brian Crombie, former chief financial officer; John Miszuk, former vice president, controller, and assistant secretary; and Kenneth G. Howling, former chief financial officer and vice president of finance and corporate affairs.

2. The financial reporting fraud involves three accounting schemes that affected reporting periods from 2001 to 2003. They are: (1) a transaction through which Biovail, over several reporting periods in 2001 and 2002, improperly moved off its financial statements and onto the financial statements of a special purpose entity known as Pharmatech the expenses incurred in the research and development of some of Biovail's products that totaled approximately $47 million through September 30, 2002 and related liabilities that exceeded approximately $51 million through that date; (2) a fictitious bill and hold transaction that Biovail concocted to record approximately $8 million in revenue in the second quarter of 2003; and (3) the intentional misstatement of foreign exchange losses that caused Biovail's second quarter 2003 loss to be understated by about $3.9 million.

3. In addition, in October 2003, Biovail intentionally and falsely attributed nearly half of its failure to meet its third quarter 2003 earnings guidance to a truck accident involving a shipment of Biovail's product, Wellbutrin XL. Biovail intentionally misstated both the effect of the accident on Biovail's third quarter earnings as well as the value of the product involved in the truck accident. The accident, in fact, had no effect on third quarter earnings.

4. Each of Biovail's fraudulent accounting schemes had a material effect on Biovail's financial statements for the relevant quarters and years and was engineered by Biovail's senior management in order to manage Biovail's earnings. In effecting these schemes, Biovail management also intentionally deceived its auditors as to the true nature of the transactions. The truck accident misstatements were intended to and did mislead analysts and the investing public concerning the significance of Biovail's failure to meet its own earnings guidance.

5. Biovail's then-chairman and chief executive, Eugene Melnyk, also violated share ownership disclosure provisions by failing to identify in his Schedule 13D filings his beneficial ownership of Biovail shares held by several trusts he settled in the late 1990s. Melnyk transferred the Biovail shares from his personal holdings to the trusts. However, because Melnyk continued to exercise both investment and trading authority over the shares in the trusts, Melnyk remained a beneficial owner of the securities and was under a legal obligation to disclose that ownership and material changes to it.

VIOLATIONS

6. By virtue of the foregoing conduct:

a. Biovail, directly or indirectly, singly or in concert, has engaged in acts, practices, and courses of business that constitute violations of Section 17(a) of the Securities Act of 1933 (the "Securities Act") [15 U.S.C. § 77q(a)], Sections 10(b) 13(a), 13(b)(2)(A), and 13(b)(2)(B) of the Securities Exchange Act of 1934 (the "Exchange Act") [15 U.S.C. §§ 78j(b), 78m(a), 78m(b)(2)(A) and 78m(b)(2)(B)] and Rules 10b-5, 12b-20, 13a-1, and 13a-16, and Rule 302(b) of Regulation S-T [17 C.F.R. §§ 240.10b-5, 240.12b-20, 240.13a-1, 240.13a-16, and 232.302(b)].

b. Melnyk, Crombie, Miszuk, and Howling, directly or indirectly, singly or in concert, have engaged in acts, practices, and courses of business that constitute violations of Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 [17 C.F.R. § 240.10b-5].

c. Crombie, directly or indirectly, singly or in concert, has engaged in acts, practices, and courses of business that constitute violations of Section 17(a) of the Securities Act [15 U.S.C. § 77q(a)].

d. Melnyk, directly or indirectly, singly or in concert, has engaged in acts, practices, and courses of business that constitute violations of Section 13(d) of the Exchange Act [15 U.S.C. § 78m(d)] and Rules 13d-1 and 13d-2 [17 C.F.R. §§ 240.13d-1 and 240.13d-2].

e. Crombie and Miszuk, directly or indirectly, singly or in concert, have engaged in acts, practices, and courses of business that constitute violations of Section 13(b)(5) of the Exchange Act [15 U.S.C. § 78m(b)(5)] and Rules 13b2-1 and 13b2-2 [17 C.F.R. §§ 240.13b2-1 and 240.13b2-2].

f. Crombie, directly or indirectly, singly or in concert, has engaged in acts, practices, and courses of business that constitute violations of Rule 13a-14 [17 C.F.R. § 240.13a-14].

g. By virtue of the conduct described herein, Crombie and Miszuk are also each liable, pursuant to Section 20(e) of the Exchange Act, as an aider and abettor of Biovail's violations of Sections 10(b), 13(a), 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act [15 U.S.C. §§ 78j(b), 78m(a), 78m(b)(2)(A) and 78m(b)(2)(B)] and Rules 10b-5, 12b-20, 13a-1 and 13a-16 [17 C.F.R. §§ 240.10b-5, 240.12b-20, 240.13a-1 and 240.13a-16].

JURISDICTION AND VENUE

7. The Commission brings this action pursuant to the authority conferred upon it by Section 20(b) of the Securities Act [15 U.S.C. § 77t(b)] and Section 21(d)(1) of the Exchange Act [15 U.S.C. § 78u(d)(1)] seeking to restrain and permanently enjoin Biovail, Melnyk,

Crombie, Miszuk, and Howling from engaging in the acts, practices, and courses of business alleged herein. The Commission also seeks a final judgment:

a. ordering Biovail, Melnyk, Crombie, Miszuk, and Howling to disgorge any ill-gotten gains and to pay prejudgment interest thereon;

b. ordering Biovail and Crombie to pay civil money penalties pursuant to Section 20(d) of the Securities Act [15 U.S.C. § 77t(d)];

c. ordering Biovail, Melnyk, Crombie, Miszuk, and Howling to pay civil money penalties pursuant to Section 21(d)(3) of the Exchange Act [15 U.S.C. § 78u(d)(3)]; and

d. permanently barring Melnyk, Crombie, Miszuk, and Howling from acting as an officer or director of any issuer that has a class of securities registered pursuant to Section 12 of the Exchange Act [15 U.S.C. § 78l] or that is required to file reports pursuant to Section 15(d) of the Exchange Act [15 U.S.C. § 78o(d)].

8. This Court has jurisdiction over this action pursuant to Section 22(a) of the Securities Act [15 U.S.C. § 77v(a)] and Sections 21(e) and 27 of the Exchange Act [15 U.S.C. §§ 78u(e) and 78aa].

9. Venue is proper under Section 22(a) of the Securities Act [15 U.S.C. § 77v] because a registered offering of Biovail's securities took place in, among other places, the Southern District of New York. Venue is proper under Section 27 of the Exchange Act [15 U.S.C. § 78aa] because certain of the transactions, acts, practices, and courses of business alleged in this Complaint took place in the Southern District of New York.

10. Biovail and Crombie, directly or indirectly, singly or in concert, have made use of means or instruments of transportation or communication in interstate commerce, or of the mails, in connection with the transactions, acts, practices, and courses of business alleged in this Complaint.

11. Biovail, Melnyk, Crombie, Miszuk, and Howling, directly or indirectly, singly or in concert, have made use of the means and instrumentalities of interstate commerce, or of the mails, or of a facility of a national securities exchange, in connection with the transactions, acts, practices, and courses of business alleged in this Complaint.

THE DEFENDANTS

12. **Biovail Corporation,** a foreign private issuer, is a pharmaceutical company incorporated under the laws of Ontario, Canada. Its headquarters are in Mississauga, Ontario, and it has facilities in the United States, Canada, Ireland, and Puerto Rico. As a foreign private issuer, Biovail files annual reports on Form 20-F and furnishes interim financial statements to the Commission on Form 6-K. During the relevant time period, Biovail included in its annual and interim reports financial statements purportedly prepared in accordance with both U.S. and Canadian generally accepted accounting principles. Since 2006, Biovail has been providing financial statements prepared only in accordance with U.S. generally accepted accounting principles ("U.S. GAAP").

13. **Eugene Melnyk**, age 49, is a Canadian citizen and a resident of St. Philip, Barbados. Melnyk is the founder of Biovail and served as its chairman and as a director from March 1994 through June 2007. From December 2001 to October 2004, Melnyk also was

Biovail's chief executive officer. Melnyk resigned as a director and chairman of Biovail effective June 30, 2007.

14. **Brian Crombie**, age 49, is a Canadian citizen and a resident of Mississauga, Ontario. He was Biovail's chief financial officer from May 2000 to August 2004. In August 2004, Crombie was removed as chief financial officer and became Biovail's senior vice president for strategic development. As of May 2007, Crombie no longer holds any position with the Company. Crombie's compensation during the relevant time period had salary and bonus components. His bonus was dependent on several factors, including whether the Company met certain financial targets.

15. **John Miszuk**, age 55, is a Canadian citizen and a resident of Mississauga, Ontario. In 2003, he was a vice president, controller, and assistant secretary of Biovail. In March 2008, he was reassigned to a non-officer position within the Company. While Miszuk is not a chartered accountant, he was the principal accounting officer for Biovail. The controllers of all of the operating groups reported to him. Corporate legal accounting as well as the consolidated reporting group also reported to him. Miszuk also was responsible for communicating with Biovail's independent auditors. Miszuk's compensation during the relevant time period had salary and bonus components. His bonus was dependent on several factors, including whether the Company met certain financial targets.

16. **Kenneth G. Howling**, age 51, is a U.S. citizen and a resident of Toronto, Ontario. On December 6, 2006, the Company announced Howling's promotion to his current position of senior vice-president and chief financial officer. He also was the Company's chief financial officer from 1997 to 2000. From 2000 to 2003, he was Biovail's vice president of finance, and

in 2003 he assumed additional responsibilities for external communications to investors and analysts when his title changed to vice president, finance and corporate affairs. He is a certified public accountant licensed in New Jersey, but is not a Canadian chartered accountant. In March 2008, he was reassigned to a non-officer position within the Company. Howling's compensation during the relevant time period had salary and bonus components. His bonus was dependent on several factors, including whether the Company met certain financial targets.

FACTS

A. Misrepresentations Concerning the October 2003 Truck Accident

17. On September 30, 2003, a truck carrying a shipment of a Biovail product, Wellbutrin XL, left Biovail's Steinbach, Manitoba, plant bound for the North Carolina facility of a major international pharmaceutical company that distributed the product (the "Distributor"). On October 1, 2003, while en route to North Carolina, the truck was involved in a multi-vehicle traffic accident on a highway in Illinois.

18. The value of the product on the truck that was involved in the accident was about $5 million.

19. Biovail, Melnyk, Crombie, and Howling issued two press releases and made numerous other public statements declaring that the loss of revenue and income associated with the truck accident contributed significantly to Biovail's substantial revenue shortfall for the third quarter of 2003 in the amount of $10 million to $20 million, or about 23% to 38% of the total announced revenue shortfall for the quarter.

20. The press releases and other repeated public statements were materially false and misleading. The truck accident had no impact on Biovail's financial results for the quarter, as

Biovail, Melnyk, Crombie, and Howling knew or recklessly disregarded. In addition, in the press releases and other public statements, Biovail, Melnyk, Crombie, and Howling grossly overstated the revenue value of the shipment involved in the truck accident.

The Truck Accident Had No Impact on Biovail's Third Quarter Revenues

21. Under U.S. GAAP, revenue may be recognized on the sale of a product like Wellbutrin XL when, among other things, delivery of the product by the seller to the buyer has occurred.

22. Pursuant to Biovail's agreement with the Distributor, all deliveries of Wellbutrin XL were subject to the term "F.O.B., [the Distributor's] facilities in the U.S.A. (freight collect)." This "F.O.B. Destination" delivery term meant that delivery occurred – and Biovail's revenue recognition would have been appropriate – only when the product reached the Distributor's facilities in the United States.

23. Under the F.O.B. Destination shipping term – the term actually in effect – the truck accident had no impact on Biovail's third quarter financial results because the truck left Manitoba on September 30, which was too late for it to reach the Distributor's North Carolina facility prior to the end of the quarter. Under those circumstances, Biovail could not have recognized revenue resulting from the shipment regardless of the accident.

24. The deliberate misrepresentations by Melnyk, Crombie, Howling, and Biovail were based on the false premise that the delivery term was "F.O.B. Biovail," pursuant to which delivery would have occurred – and Biovail could have recognized the revenue from the sale – at the time the product left Biovail's facility.

25. However, even if the shipping term were F.O.B. Biovail, the truck accident would have had no impact on Biovail's third quarter financial results because the title to the product – and the risk associated with the accident –would have passed to the Distributor as soon as the truck left Biovail's Manitoba plant. Under those circumstances, Biovail could have recognized revenue resulting from the shipment regardless of the accident.

26. Nevertheless, Melnyk, Crombie, Howling, and Biovail repeatedly and falsely attributed the Company's third quarter revenue shortfall to the truck accident.

The October 3 Press Release and Conference Call

27. On October 3, 2003, Biovail issued a press release announcing that its third quarter 2003 "revenues [would] be below previously issued guidance and will be in the range of $215 million to $235 million and earnings per share of $0.35 to $0.45." The revenues were below the guidance the Company had issued in February 2003 by about $45 million to $65 million and the earnings per share range were below the February estimate by $0.23 at both ends of the range. This was the first time that Biovail had ever failed to meet its quarterly guidance.

28. The October 3 press release falsely attributed a significant part of the revenue shortfall to the truck accident: "Contributing significantly to this unfavorable variance was the loss of revenue and income associated with a significant in-transit shipment loss of Wellbutrin XL as a result of a traffic accident." This statement was materially false and misleading, as Melnyk, Crombie, Howling, and Biovail knew or recklessly disregarded.

29. The October 3 press release also grossly overstated the revenue value of the Wellbutrin XL shipment involved in the accident: "Revenue associated with this shipment is in

the range of $10 to $20 million." This statement was materially false and misleading, as Melnyk, Crombie, and Biovail knew or recklessly disregarded.

30. Howling wrote the October 3 press release. Howling's name also appears on the press release as the contact person.

31. Howling drafted the release based, in part, on information he received from others, including information he and Crombie received from Biovail's warehouse supervisor who was communicating with the transportation company. The information provided by the warehouse supervisor made clear that the shipment had left Biovail's warehouse on September 30, 2003 (and therefore could not have reached the Distributor's North Carolina facility by the end of the quarter) and that only one truck carrying Wellbutrin XL was involved in the accident.

32. In order to write the press release, Howling asked Crombie to quantify the value of the product on the truck. Although Crombie knew that the true value of the product on the truck involved in the accident was approximately $5 million, he provided Howling with a falsely inflated valuation of $10 to $20 million for Howling to include in the press release.

33. Melnyk, Crombie, and Biovail knew or recklessly disregarded that the statement in the October 3 press release concerning the value of the product involved in the truck accident was materially false and misleading.

34. Howling also reviewed and used an initial draft press release that Crombie had prepared earlier in the day on October 2 and forwarded to both Melnyk and Howling. Crombie's draft stated correctly: "[s]ince the supply agreement between Biovail and its licensee stipulates FOB the licensee's warehouse, the revenue on this product cannot be recognized in Q3, 2003.

The product, either the existing shipment once approved, or replacement shipment will be shipped within ten days. However, this replacement shipment and its associated revenue will now be recognized in Q4 not Q3."

35. When Crombie wrote his draft press release, he had already reviewed the language of the Wellbutrin XL agreement. He knew that the F.O.B. Destination term was in effect and, therefore, the truck accident had no impact on the Company's third quarter revenue. Likewise, upon reading Crombie's draft press release on October 2, Howling knew or recklessly disregarded what it said – *i.e.*, that the correct delivery term in effect for sales of Wellbutrin XL was F.O.B. Destination and that the accident had no impact on the revenue for the third quarter.

36. Despite the correct statements in Crombie's draft, the October 3 press release written by Howling, reviewed and edited by Melnyk and Crombie, and ultimately issued by Howling's office, under his supervision, for the Company was false and misleading because, among other things, it falsely stated that the truck accident contributed significantly to the third quarter revenue shortfall.

37. Also on October 3, Melnyk, Crombie, and Howling participated in a conference call with analysts in which Melnyk falsely stated: "This accident will have a negative financial impact on Biovail's third quarter revenues." Melnyk later in the call said again, "It is a third quarter item." Melnyk, Crombie, Howling, and Biovail knew or recklessly disregarded that these statements by Melnyk were materially false and misleading.

38. On the same conference call, Crombie falsely said, "The unfortunate incident . . . will have a material negative effect on Biovail's third quarter revenue and earnings." He also falsely told the analysts on the call, "Our contract with [the Distributor] has title change in

Manitoba when it leaves our shipping dock." In fact, as Melnyk, Crombie, and Howling knew or recklessly disregarded, title to the product would change only upon arrival at the Distributor's facility in the United States, and therefore Biovail could not have recognized third quarter revenue on the shipment even if the accident had not occurred.

39. On the same call, Crombie referred to the value of the shipment as "$15 million to $20 million" – three to four times the actual revenue value. He also noted, "As a result of this accident, Biovail currently estimates that its total third quarter revenues from Wellbutrin XL will now be below $10 million." Melnyk, Crombie, and Biovail knew or recklessly disregarded that these statements were materially false and misleading.

40. Howling participated in the October 3 conference call and helped prepare the script for it. Although he knew or recklessly disregarded that the truck accident had no impact on Biovail's third quarter financial results, he remained silent during the call and did not correct any of the materially false and misleading statements that Melnyk and Crombie made during the call claiming that the accident did have such an impact.

41. Following the October 3 press release and conference call, Howling was inundated with numerous inquiries from investors, analysts, and the financial press seeking details regarding the effect of the accident on Biovail's third quarter revenues. These queries included whether Biovail would have been able to record the revenue associated with this shipment in the third quarter even if the accident had not taken place. In response to these inquiries, Howling continued to state falsely that the Wellbutrin XL agreement would have allowed Biovail to recognize revenue in the ordinary course as of the date of shipment from

Biovail's warehouse but that the Company was unable to record the revenue in the third quarter in this case because of the accident.

42. On October 3, Howling also received information detailing the cost of goods that were lost in the accident. In order to respond to the inquiries from investors, analysts, and the financial press, Howling independently calculated the actual revenue associated with the Wellbutrin XL lost in the accident. His calculations demonstrated that, in order for even the low end of the valuation published by the Company – $10 million – to have been accurate, the product would have had to carry an 80% revenue margin. Howling knew or recklessly disregarded that the actual margin for Wellbutrin XL was substantially less than 80%. Nevertheless, he continued to state falsely in response to inquiries he received from the public following the October 3 press release and conference call that the damaged product was valued at $10-20 million.

The October 8 Press Release

43. On October 8, 2003, an investment bank research analyst issued a research report with a Biovail sell rating (the "Report"). In the Report, the analyst questioned both Biovail's valuation of the product lost due to the accident as well as the Company's assertion of when title to the product transferred.

44. Howling received a copy of the Report on October 8 and he promptly forwarded to Melnyk and Crombie the portion of the Report questioning the value of the shipment involved in the truck accident, suggesting that someone in finance draft responses to the issues raised. Soon after, Howling forwarded the entire Report to Melnyk and Crombie.

45. Following circulation of the Report, other research analysts asked Howling many questions about the quantity of product on the truck, the value of that product, and the wide range of value Biovail had given on October 3.

46. Also on October 8, an employee at the Distributor called and e-mailed Howling in order to correct some of the misstatements in the October 3 press release and conference call. The e-mail, which Howling forwarded to Melnyk and Crombie, said that Biovail's conference call statement on when title to the product passed to the Distributor was "an incorrect statement, as the [agreement between Biovail and the Distributor] provides that title to and risk of loss with respect to the product would not have passed to [the Distributor] until the product was delivered to [the Distributor's] facility in the U.S.A." Howling assumed responsibility for speaking to the employee of the Distributor prior to issuing any further press releases on the subject.

47. Hours later – while under fire from analysts and investors as a result of the Report – Biovail issued a second press release that announced the recovery and salability of the product involved in the accident and "re-confirm[ed] that the sales value of these goods is within previously stated guidance." Melnyk dictated the October 8 press release, which both Crombie and Howling reviewed and edited prior to its issuance. The October 8 press release was issued by Howling's office, under his supervision, and his name appears on it as the contact person. Biovail issued this press release even though Howling had been unable to speak with the employee of the Distributor before the release was issued.

48. The October 8 press release was deliberately and materially false and misleading. Even though Melnyk, Crombie, Howling, and Biovail all knew or recklessly disregarded that the

truck accident had no impact on third quarter revenues, the October 8 press release was silent on that subject. This was a material omission.

49. Moreover, Melnyk, Crombie, Howling, and Biovail knew or recklessly disregarded that the statement in the October 8 press release reconfirming the October 3 guidance concerning the value of the product involved in the accident was materially false and misleading because they knew that the value in the October 3 press release was deliberately overstated.

October 10-15 Road Show

50. In the days immediately following October 8, there was a perception inside Biovail that management's credibility had been attacked by the Report on October 8. Biovail wanted to address these credibility concerns and other issues with investors, including any questions about Biovail's ability to meet anticipated market demand for Wellbutrin XL.

51. To this end, on October 10, 13, 14, and 15, 2003, Biovail executives Melnyk, Crombie, and Howling conducted a road show in New York, Boston, and other cities to meet with market analysts and investors. During the road show, the Biovail executives talked about, among other things, the matters discussed in the Company's October 3, 2003 press release.

52. The road show included a power point presentation prepared by Howling that repeated falsely that the truck accident's impact on Biovail's third quarter 2003 revenue was $10 to $20 million. In addition to the slides, the executives at the road show provided commentary and answered questions reiterating the false statements in the October 3 press release. At the time of these misstatements, Melnyk, Crombie, Howling, and Biovail all knew or deliberately disregarded that the statements attributing part of the third quarter revenue shortfall to the truck

accident were materially false and misleading. Melnyk, Crombie, Howling, and Biovail also knew or recklessly disregarded that the road show statements concerning the value of the product on the truck were materially false and misleading.

The Misstatements Were Never Fully Corrected

53. On March 3, 2004, in its annual earnings release Biovail finally acknowledged that the revenue associated with the product involved in the truck accident was only about $5 million rather than the $10 to $20 million previously stated on October 3, 2003. Even this release, however, did not acknowledge that the truck accident had no impact on Biovail's third quarter revenues.

B. Material Misstatements Related to Pharmatech

54. In mid-2001, Biovail sought to increase net income by removing from its books the research and development costs associated with a key mid-term product pipeline. To achieve this goal, Biovail created a special purpose entity, Pharmaceutical Technologies Corp. (known as Pharmatech), to carry those costs.

55. Despite the fact that research and development costs were expected to be in the tens of millions of dollars, with some estimates as high as $120 million, Pharmatech's sole shareholder, whom Biovail secured, invested only $1 million in the company, of which $350,000 was immediately refundable as a fee.

56. Biovail secured financing for Pharmatech from its own lender (the "Bank"), based on Crombie's assurances that, if at any time the Bank chose not to renew the Pharmatech financing, Biovail would likely purchase Pharmatech and retire the debt.

57. Crombie and Biovail deliberately and fraudulently orchestrated the Pharmatech arrangement as a means to avoid recording on Biovail's books and records and reporting on its financial statements the expenses and liabilities related to the research and development of certain Biovail products. Crombie knew, and told the Bank, that it was probable that Biovail would repay Pharmatech's debt to the Bank when it first came due after one year, regardless of the outcome of the research and development at that point, if the Bank did not renew the financing. Crombie and Biovail understood that under those circumstances U.S. GAAP required Biovail to record Pharmatech's expenses and liabilities and to include them on its own financial statements.

58. Nevertheless, Crombie and Biovail deliberately did not recognize and record Pharmatech's liabilities or charge its research development costs to expense as incurred on Biovail's books and records and did not include them on Biovail's financial statements. Instead, Crombie intentionally misled Biovail's auditors as to the true nature of the arrangement in order to secure from the auditors an opinion letter supporting Biovail's accounting for the arrangement.

The Applicable Accounting Principles

59. The applicable U.S. GAAP guidance in Statement of Financial Accounting Standards No. 68, *Research and Development Arrangements* ("SFAS 68"), provides that an enterprise that is a party to a research and development arrangement that allows it to obtain the results of research and development funded partially or entirely by others must estimate and recognize the liability on its own books and records if the enterprise is obligated to repay any of the funds provided by the other parties, regardless of the outcome of the research and development. Under such circumstances, SFAS 68 also requires the enterprise to charge the research and development costs to expense as incurred.

60. Even in the absence of a written agreement or contract requiring repayment by the enterprise, SFAS 68 sets forth a presumption that the enterprise has an obligation to repay the other parties if surrounding conditions suggest that it is probable that the enterprise will repay any of the funds regardless of the outcome of the research and development. That presumption can be overcome only by substantial evidence to the contrary. "Probable" in this context means that repayment is likely.

61. SFAS 68 provides examples of circumstances under which there is a presumption of a repayment obligation, including, among others, that the enterprise has indicated an intent to repay all or a portion of the funds provided regardless of the outcome of the research and development.

The Agreements Between Biovail and Pharmatech

62. Pharmatech was incorporated in Barbados on June 29, 2001 and, on the same day, it entered into a Product Development and Royalty Agreement with Biovail's Barbados

subsidiary, Biovail Laboratories, Inc. In this agreement, Pharmatech agreed to pay all the costs and expenses required to obtain regulatory approval of certain products in Biovail's midterm product pipeline, and Biovail granted Pharmatech a license to use the technologies necessary to develop the products.

63. Biovail also agreed to pay Pharmatech a royalty calculated as a percentage of the net sales of each successfully developed and approved product. Although the royalty payments would continue for ten years after each product's launch, Biovail could terminate the royalty obligation at any time upon thirty days notice and instead pay a contractually specified amount that increased over time depending on the date of the termination notice.

64. In a related Advisory Agreement, Biovail also agreed to guide Pharmatech in the development of the products.

65. The products included in the Pharmatech portfolio were those that could be launched within two to five years. The intention was to improve on drugs that were already in the market by providing new drug delivery formulations that could enhance effectiveness and increase patient compliance.

66. Several of the products were being developed to use controlled release technology that allowed for the gradual and predictable release of active ingredients over twelve or twenty four hours. Other products were to use the FlashDose drug delivery system, in which the product dissolves rapidly on the user's tongue.

67. Biovail had obtained the FlashDose technology in November 1999 by acquiring another pharmaceutical company for approximately $250 million. That purchase was a significant acquisition and both the FlashDose and controlled release technologies were

important to Biovail. Although in June 2001, it was not certain that the FlashDose or controlled release technologies could be combined effectively and safely with any of the products in the Pharmatech portfolio, Biovail told the Bank that the products comprised its key mid-term product pipeline.

68. In connection with the agreement with Pharmatech, Biovail also entered into a Share Option Agreement with Pharmatech's sole stockholder. This agreement permitted Biovail to purchase all of the stockholder's Pharmatech shares at any time until December 31, 2006, in exchange for a fixed purchase price that ranged from $1.25 million to $5 million depending on the date Biovail exercised the share purchase option.

Pharmatech's Agreement with the Bank

69. Although Pharmatech agreed to pay the costs of developing the products, it had little working capital with which to do so. The sole stockholder's capital investment was just $1 million and the new company had no sources of revenue and no assets other than the potential future royalty payments and the license from Biovail to use the FlashDose and controlled release technologies in developing the products.

70. To address this problem Crombie approached several potential lenders but ultimately only the Bank agreed to provide financing. Since the 1990's the Bank had served as Biovail's primary lender extending hundreds of millions of dollars in financing to Biovail through a credit facility.

71. In a June 29, 2001 agreement, the Bank agreed to extend credit to Pharmatech in the maximum aggregate amount of $60 million for 364 days, at which time the outstanding debt would become due and payable. Pharmatech, however, could seek a 364-day extension of the

credit facility, which the Bank could grant or deny in its discretion. As collateral, Pharmatech granted the Bank a security interest in the Product Development and Royalty Agreement, including the potential future royalty payments and the license to use the crucial technology to develop the products. In the event of default, the Bank would also have the right to assign Pharmatech's rights under the agreement to a third party, including the right to continue development of the products using the FlashDose and controlled release technologies.

72. In connection with the financing, Biovail provided a comfort letter addressed to the Bank stating that, if Biovail exercised its share purchase option, Biovail would arrange to repay in full on or before June 30, 2004 any outstanding balance then due. Thus, the probability that Biovail would repay Pharmatech's debt to the Bank turned on the likelihood that Biovail would exercise its share purchase option if the Bank did not renew the loan after one year.

73. Crombie made clear to the Bank during the discussions about financing that Biovail probably would repay the Bank regardless of the outcome of the product development. Specifically, Crombie told the Bank that: (1) Biovail had a compelling business incentive to acquire Pharmatech and repay the loan because Biovail would want the royalties from any successfully developed products; (2) in any event, Biovail did not want its competitors acquiring access to the license to use the FlashDose (which Biovail had paid $250 million to acquire) or controlled release technologies that Biovail had assigned to Pharmatech; and (3) the Bank had an effective "annual put" to Biovail, meaning that, when the credit facility came up for review after one year, if the Bank declined to extend the financing, the Bank could expect Biovail to acquire Pharmatech and repay the indebtedness.

The Auditors' Opinion Letter

74. In connection with the Pharmatech transaction, Biovail obtained from its auditors an opinion letter concerning the accounting implications of the transaction. Among other things, the opinion letter, dated June 29, 2001, analyzed the deal in light of SFAS 68. The letter contains a table summarizing in one column the factors specified in SFAS 68 and in a parallel column the information Crombie provided in June 2001 to the audit partner and other members of the audit team on each of those factors. Crombie knew that the auditors would rely upon that factual information in issuing their opinion, and they did rely on it.

75. Specifically, in order to secure the opinion letter from Biovail's auditors, in June 2001, Crombie made the following misstatements to the audit partner and other members of the audit team:

- Crombie told the auditors that Biovail's management did not believe that it was probable that Biovail would repay the amounts being advanced and that the funding provided by others should not be recorded as a liability.
- Crombie told the auditors that Biovail had not provided any explicit or implicit undertakings to any parties involved in the transaction to repay all or a portion of the funds provided.
- Crombie told the auditors that Biovail's management did not currently believe that it was probable that it would choose to purchase the common shares of Pharmatech rather than incur any penalty.

76. Crombie also falsely stated during regular conversations in June 2001 with the audit partner and other members of the audit team that he gave no comfort to the Bank in regard to exercising any options and did not provide any guaranties, or puts, or protections, or anything of the like.

77. Crombie's statements to the auditors were materially false and misleading because he was telling the accountants the opposite of what he was contemporaneously telling the Bank. In particular, Crombie failed to tell the auditors that he had told the Bank that, in the event of a Pharmatech default, Biovail would have a compelling business incentive to exercise its option to acquire Pharmatech and repay the indebtedness to the Bank. Crombie also did not tell the auditors that he had told the Bank that the annual loan renewal mechanism was effectively an "annual put" to Biovail. Similarly, Crombie did not tell the auditors that he had told the Bank that Biovail would not want to see the technology license in which the Bank had taken a security interest fall into the hands of Biovail's competitors. These were material false statements and omissions.

78. Crombie was well aware of the U.S. GAAP requirements for research and development arrangements because of his involvement in Biovail's previous such arrangements. Crombie deceived the auditors because he specifically understood that the auditors would not issue the opinion letter regarding Pharmatech if he told them the truth.

Biovail's Purchase of Pharmatech When the Bank Did Not Renew the Financing

79. At the conclusion of the initial year of financing, in June 2002, the Bank extended Pharmatech's financing but only for six more months, until December 31, 2002. As early as October 2002, Biovail management began to conclude that the Bank would neither renew the credit facility on December 31, 2002 nor increase its limit. Finally, on December 24, 2002, Crombie learned definitively that the Bank would not extend any additional funds to Pharmatech.

80. Three days later, Biovail sent a letter notifying the Pharmatech stockholder that Biovail intended to exercise the purchase option. Consistent with the "put" representations

Crombie had made to the Bank, Biovail bought Pharmatech when the Bank decided not to extend additional financing, and repaid the Bank in full. Biovail's actions confirm that the Company's intention always was to exercise its purchase option and repay the Bank if the credit facility was not extended.

False and Misleading Public Filings

81. Biovail's interim financial statements for the quarter ended September 30, 2001 and for the nine months ended September 30, 2001 were furnished to the Commission on Form 6-K on November 13, 2001. Biovail's interim financial statements for the quarter ended March 31, 2002 were furnished to the Commission on Form 6-K on May 30, 2002. Biovail's interim financial statements for the quarter ended June 30, 2002 were furnished to the Commission on Form 6-K on August 29, 2002. On that date Crombie signed a certification stating the Form 6-K report "fairly presents, in all material respects, the financial condition and results of operations of the Company." Crombie and Biovail knew, or recklessly disregarded, that this representation was materially false and misleading.

82. Biovail's interim financial statements for the quarter ended September 30, 2002 were furnished to the Commission on Form 6-K on November 25, 2002. On that date Crombie signed a certification stating the Form 6-K report "fairly presents, in all material respects, the financial condition and results of operations of the Company." Crombie and Biovail knew, or recklessly disregarded, that this representation was materially false and misleading.

83. Biovail's annual report for the year ended December 31, 2001 was signed by Crombie and filed with the Commission on Form 20-F on May 17, 2002. Biovail's annual report for the year ended December 31, 2002 was signed by Crombie and filed with the

Commission on May 20, 2003. On that date, Crombie also signed a certification stating that the Form 20-F report "fairly presents, in all material respects, the financial condition and results of operations of the Company." Crombie and Biovail knew, or recklessly disregarded, that this representation was materially false and misleading.

84. As a direct result of Crombie's and Biovail's intentional failure to record on Biovail's books and records a total of approximately $47 million in Pharmatech's expenses and more than approximately $51 million in liabilities related to the research and development through September 30, 2002, Biovail's financial statements were materially misstated. In addition, during the fourth quarter of 2002, Biovail did not charge to expense as incurred more than $10 million in additional Pharmatech expenses and did not timely recognize and record on Biovail's books and records additional related liabilities that Pharmatech incurred during that quarter.

85. Specifically, Biovail's financial reports were materially false and misleading in that they did not include Pharmatech's research and development expenses, causing: (1) net income to be overstated by approximately 50% in the third quarter 2001, 32% in the 2001 annual financial statements, 15% in the first quarter 2002, 18% in the second quarter 2002, and 16% in the third quarter 2002, and understated by approximately 17% in the 2002 annual financial statements; and (2) net income excluding certain charges to be overstated by approximately 25% in the third quarter 2001, 12% in the 2001 annual financial statements, 16% in the third quarter 2002, and 17% in the 2002 annual financial statements.

86. Biovail's balance sheets included in the financial reports also were materially false and misleading because they did not include Pharmatech's liability to the Bank, causing

Biovail's total liabilities to be understated by approximately 2% in the third quarter 2001, 11% at year-end 2001, 5% in the first quarter 2002, 5% in the second quarter 2002, and 7% in the third quarter 2002.

87. Crombie and Biovail knew, or recklessly disregarded, that the financial statements identified above were materially false and misleading.

88. During the period when Biovail's financial statements were intentionally and materially misstated as a result of the Pharmatech fraud, Biovail conducted a registered offering in which it sold 12.5 million of its common shares and raised gross proceeds of approximately $587.5 million. The prospectus supplement for this offering, filed on November 15, 2001, incorporated by reference Biovail's intentionally and materially false and misleading financial statements for the nine months ended September 30, 2001, furnished to the Commission on the Company's Form 6-K dated November 13, 2001.

89. Crombie and Biovail knew, or recklessly disregarded, that Biovail's materially false and misleading financial statements for the nine months ended September 30, 2001, were incorporated by reference into the prospectus supplement dated November 15, 2001.

C. A Sham Bill and Hold Transaction in June 2003

90. In the second quarter of 2003, both product revenue and total revenue were below even the low end of Biovail's previously issued guidance for the quarter, and the Company was in danger of missing earnings expectations for the first time in its history. In particular, Biovail had not sold any Wellbutrin XL, a drug that analysts considered crucial to the Company's health and whose sales potential had led some analysts to issue a buy recommendation for the Company.

91. Rather than acknowledge the Company's poor performance that quarter, Crombie, Miszuk, and Biovail fraudulently and improperly recognized and recorded approximately $8 million in additional revenue from a phony sale of Wellbutrin XL. As a result, for the quarter ended June 30, 2003, Biovail's net loss was intentionally and materially understated by approximately 80% in its interim financial statements that Biovail furnished to the Commission on Form 6-K on August 29, 2003. Moreover, by recognizing the $8 million in revenue from the phony sale in the second quarter of 2003, Biovail was able to avoid reporting a decrease in overall product revenue relative to the second quarter of 2002, which analysts would have considered a bad trend.

Biovail's Wellbutrin XL Agreement

92. Through subsidiaries, Biovail and the Distributor entered into a Development, License and CoPromotion Agreement in 2001. Pursuant to the agreement, and subject to FDA approval, Biovail was to manufacture Wellbutrin XL and sell it to the Distributor, which would distribute the product to third-party purchasers. The agreement required Biovail to produce Wellbutrin XL to be used for two purposes: (1) as sample product that Biovail would deliver in bulk to the Distributor and that the Distributor would package and distribute to physicians as a promotional tool; and (2) as trade product that Biovail would package in bottles labeled in accordance with the FDA's requirements and that the Distributor would sell at a commercial price upon FDA approval.

93. As modified in December 2002, the agreement provided different prices for the differing dosages of sample product and trade product. Biovail sold sample pills to the Distributor at fixed prices per tablet, effectively at cost and, at the start of the product launch, at a

loss. Biovail's Wellbutrin XL revenues for trade product were tied to the Distributor's net revenues from its sales to third parties. The agreement provided that Biovail would invoice trade product shipped to the Distributor at a fixed percentage of the Distributor's estimated net sales revenues and the invoicing percentage would rise as the Distributor's actual net sales increased over time. To the extent that the Distributor's estimate of its net sales revenues was different from the actual net sales revenue, the agreement contemplated a quarterly reconciliation process.

94. The FDA issued a letter on June 26, 2003 stating that Wellbutrin XL was "approvable," which meant that the FDA required further information before the new drug application could be approved. Among other things, the FDA's June 26 letter requested revised draft labeling for the product. The FDA did not finally approve Wellbutrin XL until August 29, 2003.

Biovail's Need to Generate Trade Product Revenue in June 2003

95. On February 7, 2003 Biovail published earnings guidance for its fiscal year 2003. It projected second quarter earnings per share between $0.43 and $0.50, third quarter earnings per share between $0.58 and $0.68, and annual sales of Wellbutrin XL of between $75 million and $150 million.

96. Wellbutrin XL was a key component of these earnings projections. It was widely expected that Wellbutrin XL would be the most significant product launch in the Company's history. The product, however, could not launch until it received FDA approval. When, by early June 2003, the FDA still had not yet approved Wellbutrin XL, Biovail executives became concerned because it was clear that Biovail would not meet its second quarter earnings projections unless it sold Wellbutrin XL trade product by June 30.

97. Although Biovail needed to produce prior to approval enough Wellbutrin XL trade product to enable the Distributor to launch the product promptly, it was risky to manufacture too many pills before the FDA had determined as part of the approval process what the product's shelf life would be because the Distributor could return stale trade pills to Biovail. Sample product, however, because it would be given away rather than sold, could be distributed up until expiration.

98. In April and May 2003 the Distributor submitted purchase orders for the delivery of Wellbutrin XL sample pills in June and for delivery of trade product (contingent on FDA approval of the trade product packaging) in July.

99. There were two reasons why the Distributor sought delivery of sample pills before trade pills: (1) under the agreement, the Distributor was responsible for packaging sample pills and wanted sufficient quantities on hand early so it could prepare for the launch; and (2) there was a risk that trade pills could expire unused if they were produced too early.

100. By the middle of June 2003, Biovail had not filled the Distributor's pending orders for sample product. At the time, Biovail was experiencing manufacturing problems and, as a result, was unable to manufacture sufficient quantities to fill the sample orders. In addition, filling sample orders generated no income for Biovail. If Biovail had invoiced and shipped the inventory as samples during June, it would have sustained a loss because the cost of goods sold exceeded the contractual sample prices.

Crombie's Demand for a Trade Product Order in June

101. Even though Crombie knew about the production problems, he complained in a June 19, 2003 letter to the Distributor that Biovail needed the Distributor to place an order for

trade product for June delivery "so that Biovail could be assured that it could book the revenue associated with those shipments [of trade product] in Q2 of 2003." He proposed in his letter to sell to the Distributor as trade product "all of our current production" of Wellbutrin XL.

102. The Distributor acquiesced in Crombie's demand for a June order for trade product in view of Biovail's threat to turn its manufacturing capacity to other products, since that could have caused a delay in the Wellbutrin XL launch.

103. On June 20, 2003, the Distributor placed an order for 27.1 million tablets of trade product. Since FDA approval was still pending, Biovail could not label the product so the Distributor agreed to let Biovail hold the product awaiting FDA approval and packaging. Although Biovail had not manufactured enough pills to meet the order, Biovail purported to earmark the entire then-existing inventory of Wellbutrin XL in its warehouse, approximately 18 million pills, to fill this "bill and hold" order.

104. On June 30, 2003, Biovail invoiced the Distributor approximately $8 million for the product, and recorded a sale at a price that was slightly reduced from the usual trade prices to reflect that the packaging would not be done – or invoiced – until after FDA approval. The parties did not agree, however, on a fixed schedule for delivery of the product because the date of FDA approval was not yet known.

Applicable Accounting Principles

105. Under U.S. GAAP, revenue may be recognized when it is realized or realizable and earned. Among other things, U.S. GAAP requires that the seller complete its performance under the contract, which in this case required that Biovail (1) manufacture the Wellbutrin XL pills; and (2) deliver those pills to the Distributor; (3) at a fixed or determinable price.

106. Ordinarily, revenue may be recognized only when delivery of the product by the seller to the buyer has occurred. Under certain limited circumstances a company may recognize revenue even before it has shipped the product. This type of transaction is commonly known as a "bill and hold transaction."

107. A legitimate bill and hold transaction permits revenue recognition before delivery provided the following additional criteria under U.S. GAAP are met:

(a) The risk of ownership must have passed to the buyer;

(b) The customer must have made a fixed commitment to purchase the goods, preferably reflected in written documentation;

(c) The buyer, not the seller, must request that the transaction be on a bill and hold basis. The buyer must have a substantial business purpose for ordering the goods on a bill and hold basis;

(d) There must be a fixed schedule for delivery of the goods. The date for delivery must be reasonable and must be consistent with the buyer's business purpose (*e.g.*, storage periods are customary in the industry);

(e) The seller must not have retained any specific performance obligations such that the earnings process is not complete;

(f) The ordered goods must have been segregated from the seller's inventory and not be subject to being used to fill other orders; and

(g) The goods must be complete and ready for shipment.

108. The requirements of U.S. GAAP are summarized in Staff Accounting Bulletin No. 101 - *Revenue Recognition in Financial Statements* ("SAB 101"). The purpose of these requirements is, in part, to prevent companies from selling the same product twice – which is, among other things, what Biovail did here.

109. At the time of the transaction, Crombie and Miszuk both reviewed SAB 101 and understood the requirements under U.S. GAAP for a valid bill and hold transaction. This was a

unique transaction for Biovail, which had not previously made any sales on a bill and hold basis. Despite their unfamiliarity with this type of transaction, Crombie and Miszuk did not discuss the bill and hold transaction with the Company's independent auditors at the time of the transaction to confirm that the revenue recognition requirements were properly met. Nor did they discuss this transaction with any of the chartered accountants who worked for the Company or the subsidiary of the Company on whose books the transaction was recorded.

110. One requirement for bill and hold transactions that was plainly and deliberately flouted was the requirement that the ordered goods be segregated from the seller's inventory and not be subject to being used to fill other orders. Here, the goods supposedly sold in the sham bill and hold transaction constituted all of Biovail's inventory at that time. Consequently, there was no real segregation of Wellbutrin XL at Biovail's warehouse. Moreover, these pills were very soon thereafter designated by Miszuk and Crombie to fill the Distributor's pending orders for sample product and were shipped with new invoices at different and much lower prices – the sample prices.

The Pills Switch

111. The pills that Biovail was required to segregate to fill the June 30 bill and hold transaction were not fungible with later-produced pills because they were subject to an earlier expiration date. Although no one knew prior to FDA approval what the exact expiration date for trade product would be, Crombie and Miszuk believed in June that all of the tablets then in Biovail's inventory – which were supposedly sold to the Distributor in the purported bill and hold transaction – were already too old for trade use. To avoid potential returns of such stale pills by the Distributor, and in an attempt to fill the Distributor's orders for sample pills that had

been pending since April, Crombie and Miszuk, before the close of Biovail's second quarter books (and no later than mid-July), designated for shipment to the Distributor as sample product the very same pills that Biovail supposedly had designated and segregated for the purported June 30 bill and hold transaction. Thereafter, Crombie and Miszuk invoiced and shipped these same pills at the lower sample price instead of the higher trade price reflected on the original June 30 invoices and the Company's books. In this way, Crombie and Miszuk sold the same pills twice, at two different prices, to fill two different orders.

112. Crombie and Miszuk then invented a rationale by which Biovail purportedly could still recognize the trade sale revenue in the second quarter. They decided to replace the pills that would now be shipped as sample pills at the lower sample prices with newer pills that would now purport to be the subject of the June 30 sale.

113. Crombie's and Miszuk's scheme was promptly implemented. By July 18, Biovail sent the Distributor various schedules showing that Biovail intended to ship to the Distributor under sample invoices and at the lower sample prices the very same pills that were the subject of the June 30 trade sale invoices at the higher, trade prices. And Crombie and Miszuk ultimately shipped these pills to the Distributor under new invoices at sample prices. The original June 30 trade sale invoices were never paid and eventually were withdrawn through issuance of credit memos.

114. As of mid-July, however, as Miszuk and Crombie both knew, Biovail had not yet manufactured the additional pills needed to replace the pills purportedly segregated for the June 30 trade sale. Thus, there were not sufficient pills in existence at any time prior to the close of the second quarter books to apply to the June 30 trade sale once Crombie and Miszuk designated

all of the pills then in existence to fill the sample orders. Accordingly, Biovail never really implemented a pill-for-pill substitution to replace the purportedly segregated pills with newly manufactured pills. Miszuk and Crombie knew this prior to the close of Biovail's second quarter books and records or were reckless in not knowing this.

115. Crombie and Miszuk did not discuss with Biovail's independent auditors their scheme to replace the supposedly segregated pills. They did not seek any guidance from them as to whether the requirements of U.S. GAAP for revenue recognition generally or for a bill and hold transaction could be met by replacing the pills. Instead, in meetings with Biovail's independent auditors on July 23 and July 25, Crombie and Miszuk led the auditors to believe that a shipment of trade product had actually occurred on June 30, which was not true. Miszuk also falsely told the auditors in connection with their quarterly review that pricing on the June 30 trade product sale was fixed even after he and Crombie had decided to ship the same pills supposedly sold in that transaction to the Distributor at the lower sample prices. Crombie and Miszuk similarly did not discuss with the chartered accountants who worked for the Company (or the Company's subsidiary on whose books the transaction was recorded) their scheme to replace the segregated pills.

Intentionally and Materially False and Misleading Public Statements

116. In late July, Biovail closed its books on the second quarter still recognizing improperly the approximately $8 million in revenue in connection with the June 30 trade product sale. On July 29, 2003, Biovail issued an earnings release for the quarter ended June 30, 2003 that both Crombie and Miszuk reviewed before its issuance. On the same day, Biovail conducted a conference call with analysts to discuss the Company's financial results for the second quarter.

117. When Biovail closed its books for the quarter ended June 30, 2003 and when the Company announced its second quarter results on July 29, 2003, Crombie, Miszuk, and Biovail knew, or recklessly disregarded, that the requirements under U.S. GAAP for revenue recognition for a bill and hold transaction were not satisfied with respect to the Wellbutrin XL trade product sale transaction that purportedly occurred on June 30, 2003. Specifically, Crombie, Miszuk, and Biovail knew, or recklessly disregarded, among other things, that: (a) as of June 30, 2003 there was no fixed schedule for delivery of the goods because FDA approval for Wellbutrin XL still had not occurred; (b) the Distributor had not agreed to pay the higher trade price for product it used as sample product; (c) the pills supposedly segregated for the June 30, 2003 trade sale comprised all of Biovail's Wellbutrin XL tablets as of June 30, 2003,; and (d) Biovail had not manufactured any – or enough – other pills as of June 30 or as of the date when Biovail's second quarter books were closed in July to replace the supposedly segregated pills that Crombie and Miszuk designated for shipment to the Distributor to fill the Distributor's other pending orders for sample product at the lower sample prices.

118. The second quarter earnings announced by Biovail appeared to meet the Company's guidance for the second quarter. As a direct result of the improper recognition of revenue on the phony bill and hold transaction, the July 29, 2003 earnings release was intentionally and materially false and misleading. Specifically, the earnings release understated the Company's net loss for the quarter by approximately 80% and overstated the Company's net income (excluding acquired R&D) for the quarter by about 5%.

119. Crombie participated in the conference call on July 29, 2003, during which Howling said, "Additionally, in the second-quarter 2003, approximately $8 million of Wellbutrin XL was supplied to [the Distributor]." Although Crombie knew or recklessly disregarded at the time of the conference call that the requirements under U.S. GAAP for revenue recognition for a purported bill and hold transaction were not satisfied, he omitted to correct Howling's misstatement.

120. During August, after the Distributor began receiving the shipments of sample product, the Distributor notified Biovail that, because the August sample invoices identified the same tablets that were associated with the June 30 trade invoices, the Distributor would not process the June 30 trade invoices at that time. This message was forwarded to Crombie and Miszuk on August 14, 2003.

121. By no later than August 29, 2003, Miszuk, Crombie, and Biovail knew or recklessly disregarded, among other things, that during August the Distributor had refused to process the June 30 invoices for the trade product sale because Biovail was shipping the same pills under sample invoices at the lower sample prices.

122. Nevertheless, on August 29, 2003, the Company furnished to the Commission on Form 6-K Biovail's second quarter financial statements that were intentionally and materially false and misleading. Specifically, as a direct result of the improper recognition of revenue on the phony bill and hold transaction, the Company's net loss was understated by approximately 80%.

123. Miszuk signed this Form 6-K and Crombie also signed a statement that the Form 6-K report "fairly presents, in all material respects, the financial condition and results of operations of the Company." At that time, Crombie, Miszuk, and Biovail knew, or recklessly disregarded that the financial statements, and Crombie's statement, were intentionally and materially false and misleading because the revenue recognition on the purported June 30 trade product sale included in the second quarter financial statements was not in accordance with U.S. GAAP.

124. The next business day, on September 1, 2003, Biovail issued two credit memos to the Distributor voiding the two unpaid June 30 trade invoices.

125. On May 14, 2004, Biovail furnished to the Commission on Form 6-K/A restated financial statements for the quarter ended June 30, 2003. This restatement corrected material misstatements resulting from the previously unrecorded and unreported foreign exchange loss discussed below. But in this 2004 amendment, Biovail continued to reflect the approximately $8 million in revenue and about $4 million in earnings from the phony June 30 bill and hold transaction, causing the restated financial statements to understate net loss by about 45%. Miszuk signed this Form 6-K/A and Crombie also signed a statement that the Form 6-K/A report "fairly presents, in all material respects, the financial condition and results of operations of the

Company." At that time, Crombie, Miszuk, and Biovail knew or recklessly disregarded that the financial statements, and Crombie's statement, were materially false and misleading because the revenue recognition on the purported June 30 trade product sale included in the second quarter financial statements was not in accordance with U.S. GAAP.

126. Biovail's annual report for the year ended December 31, 2003 was signed by Crombie and filed with the Commission on May 14, 2004. This report presents restated second quarter results as they appear in the Form 6-K/A furnished to the Commission the same day, and like that Form 6-K/A, these restated results continued to reflect the approximately $8 million in revenue and about $4 million in earnings from the phony June 30 bill and hold transaction, causing the restated financial results for the second quarter of 2003 set forth in the Form 20-F to understate net loss by about 45%. On May 14, 2003, Crombie also signed a certification stating, among other things, that, based on Crombie's knowledge: (1) 'this [Form 20-F] report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;" and (2) "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report[.]" At that time, Crombie, Miszuk, and Biovail knew or recklessly disregarded that the Form 20-F, and Crombie's statement, were materially false and misleading because the revenue recognition on the purported June 30 trade product sale and included in the second quarter financial statements was not in accordance with U.S. GAAP.

Crombie's and Miszuk's Deception of Biovail's Auditors

127. Not only did Biovail, Crombie, and Miszuk not seek advice and guidance from Biovail's auditors concerning whether the bill and hold accounting was proper, but Crombie and Miszuk also made material misstatements and omissions about the June trade order to the auditors in connection with both the second quarter review and the 2003 annual audit.

128. In connection with the quarterly review, by July 22, Miszuk told the auditors that pricing was fixed on the June trade order even though, by July 18, he and Crombie already had designated for shipment as sample pills – at the lower sample prices – the pills purportedly segregated for the bill and hold sale.

129. Also during the quarterly review, Crombie discussed with the auditors their request for a confirmation about fixed pricing. In their communications with Crombie and Miszuk on at least July 23 and July 25, the auditors referred to the June transaction as a "shipment," showing their belief that actual delivery had occurred. Neither Crombie nor Miszuk corrected this misunderstanding. They did not tell the auditors that the Company had treated the June trade product sale as a bill and hold transaction. Similarly, neither Crombie nor Miszuk told the accountants in July that they had decided to use the pills originally identified on the "bill and hold" invoices to fill the Distributor's sample orders at the lower sample prices. They also did not tell the accountants that Biovail did not have sufficient product on hand to fill both the trade order and the outstanding sample orders,

130. Miszuk and Crombie similarly failed to tell the auditors during August that the Distributor was refusing to pay the June invoices because Biovail had shipped to the Distributor the very same pills under sample invoices, that the available pills were aged and best used as

samples to avoid returns, and that the Distributor did not agree to pay trade prices if it used the pills as sample product. Crombie also falsely told the auditors in February 2004 during the year-end audit that the Distributor's non-payment of the invoices in connection with the June 2003 transaction was part of a larger problem involving the Distributor's failure to pay Biovail's invoices and had nothing to do with the specific bill and hold transaction.

131. Miszuk made additional misrepresentations in the management report, a report circulated to Biovail executives and auditors which purported to provide an overview of the Company's quarterly financial performance, including both narrative and financial statements. Prior to the circulation of the management report to Biovail's auditors on July 25 and 30, 2003, Miszuk reviewed and approved the content of the report, which he knew the auditors used as part of their review process. By including approximately $8 million in revenue associated with the purported June 30 trade product sale, Biovail's July 25 and 30, 2003 second quarter 2003 management reports were materially false in two ways: (1) they overstated income and (2) both falsely asserted that "[a]ll figures contained in [the] report [were] in accordance with U.S. GAAP."

132. Only when the auditors again sought information concerning the transaction in January and February 2004 in connection with the year-end audit —after discovering the credit memos that reversed the June 2003 transaction — did the accountants first learn that Biovail had recorded the June 30 transaction as a bill and hold. Even then, neither Miszuk nor Crombie told the auditors that Biovail had shipped and invoiced as sample product in August the pills supposedly segregated for the bill and hold transaction in June.

133. Crombie and Miszuk also misled the auditors in early 2004 about the true reason for the September 1, 2003 credit memos. They told them that Biovail had credited out the June 30 invoices so that it could issue new invoices that included packaging costs. The truth was that the Distributor had refused to pay the June 30 invoices and two sets of invoices could not have duplicate lot numbers on them.

D. Material Misstatements Concerning Unrecognized Foreign Exchange Loss

134. Concurrent with its improper attempt to record unearned revenue through the sham bill and hold transaction, Biovail also sought to conceal its weak second quarter 2003 performance by intentionally failing to record in the second quarter of 2003 approximately $3.9 million in additional losses due to foreign currency fluctuations.

135. In December 2002 Biovail's Barbados subsidiary acquired from the Wellbutrin XL Distributor the Canadian rights to two pharmaceutical products. Biovail paid a portion of the consideration in cash and borrowed the balance from the Distributor. Although the currency for the transaction was Canadian dollars, Biovail's functional currency is the U.S. dollar, and Biovail reports its financial results in U.S. dollars.

136. The U.S. GAAP guidance applicable to the translation of foreign currency statements is Statement of Financial Accounting Standards No. 52, *Foreign Currency Translation,* which provides: "All elements of financial statements shall be translated by using a current exchange rate. For assets and liabilities, the exchange rate at the balance sheet dates shall be used." Consistent with this guidance, in its 2002 year-end financial statements filed with the Commission on Form 20-F on May 21, 2003, Biovail correctly reported the outstanding loan obligation in U.S. dollars by applying the then-current exchange rate.

137. On March 31, 2003, the date of Biovail's first quarter balance sheet, the Canadian dollar had strengthened against the U.S. dollar since December 31, 2002. Instead of applying the exchange rate current as of March 31 to translate the outstanding balance due on the loan from Canadian to U.S. dollars, Biovail translated the outstanding balance using the same exchange rate that it had applied in its financial statements for the year ended December 31, 2002. As a result, Biovail's financial statements for the first quarter of 2003, furnished to the Commission on Form 6-K on May 30, 2003, overstated net income by about 9%.

138. In Biovail's financial statements for the second quarter of 2003, the Company repeated the error it had made in the first quarter and again translated the remaining balance into U.S. dollars using the same exchange rate that Biovail had applied in its annual financial statements for the year ended December 31, 2002. This time, however, the error was not inadvertent.

139. On July 8, 2003, early in the quarterly closing process, the controller for the Barbados subsidiary and Biovail's senior director of legal accounting, both chartered accountants who reported to Miszuk, told Miszuk in an e-mail that the remaining outstanding balance should be adjusted to reflect the June 30 exchange rate and that doing so would generate an additional cumulative foreign exchange loss of approximately $9 million. The senior director of legal accounting noted in the e-mail that the additional foreign exchange loss was going to cause concern at the senior management level. Miszuk reviewed the e-mail and responded to it stating: "can we discuss this on Thursday can I see some analysis on this."

140. Despite this clear identification of the issue, Miszuk and Biovail did not record this additional foreign exchange loss, which Miszuk knew, or recklessly disregarded, would have

negatively affect Biovail's second quarter financial results (and also would have nullified a significant portion of the earnings Biovail planned to recognize from the sham bill and hold transaction). Moreover, the Company would have been required to restate its first quarter financial results, something Miszuk did not want to do.

141. As a result, Biovail's interim financial statements for the quarter ended June 30, 2003, furnished to the Commission on Form 6-K on August 29, 2003, were materially misstated, intentionally or recklessly. Specifically, for the three-month period ended June 30, 2003, the Company's net loss was understated by about 80%, or approximately $3.9 million, and for the six-month period ended June 30, 2003, the Company's net income was overstated by 18%, or approximately $9.3 million. Although Miszuk knew about or recklessly disregarded the exchange rate translation error, he nevertheless signed this Form 6-K.

142. Miszuk also reviewed the July 25 and July 30 management reports and approved them for circulation to, among others, the Company's outside auditors during their second quarter review. These reports present results for both the three months and six months ended June 30, 2003. As a result of Biovail's failure to record correctly the foreign exchange loss, the three-month period is misstated in the reports by about $3.9 million and the six-month period, which includes the misstatement for the quarter ended March 31, 2003, is misstated by approximately $9.3 million. These reports also asserted falsely that all figures were in accordance with U.S. GAAP. Miszuk knew, or recklessly disregarded, that the financial statements in the management reports as well as that representation were materially false and misleading.

143. Miszuk continued to discuss the foreign exchange issue with others at Biovail during the third quarter of 2003 prior to Biovail furnishing its Form 6-K to the Commission on August 29. He acknowledged the loss in previous quarters and sought a hedging strategy. Notwithstanding his awareness of the additional loss in the first two quarters of the year, Miszuk took no steps to correct the misstated quarterly reports or even to correct the problem going forward. As a result, Biovail's third quarter financial results were also incorrect because the Company understated its quarterly net income by approximately $3.1 million, or 19%. For the nine months ended September 30, 2003, the resulting cumulative overstatement of net income was approximately $6.2 million (the $9.3 million overstatement for the first two quarters less $3.1 million understatement in the third quarter), or about 9%.

144. In its March 3, 2004 year-end and fourth quarter 2003 earnings release, Biovail announced that, "in the course of preparing its financial statements for the fourth quarter and the full year 2003, the Company determined that U.S. GAAP requires that the Canadian dollar liability be translated at current rates." The release was false and misleading in that Miszuk and Biovail first learned about the issue the previous July.

145. On May 14, 2004, Biovail furnished to the Commission, on three Forms 6-K/A, its restated interim financial statements for the first, second, and third quarters of 2003. The restatements show that, as a result of the failure to record properly the foreign exchange loss, Biovail's net income was overstated by about 9% for the first quarter, its net loss was understated by 80% for the second quarter, and its net income was understated by about 19% for the third quarter.

146. Like the March 3 earnings release, each Form 6-K/A contained a statement implying that the error was discovered during the 2003 annual audit: "During the course of the preparation of its annual consolidated financial statements, the Company determined that it had applied an inappropriate exchange rate to a Canadian dollar denominated long-term obligation." Miszuk had learned about the problem much earlier, in July 2003, but on May 14, 2004 he nevertheless signed each of these Forms 6-K/A, which Biovail furnished to the Commission the same day.

147. The cumulative impact of the misstated foreign exchange loss and the improperly recognized bill and hold revenue was a total understatement of net loss in the second quarter 2003 financial statements by approximately 89%. As a result of Crombie's and Miszuk's misconduct in connection with these two matters, Biovail improperly reported EPS of $0.52 in the second quarter, beating consensus analyst expectations ($0.47) by more than 10%. This was one of the few positive (albeit false) financial data points that Biovail reported in the second quarter of 2003 and it helped to salvage an otherwise weak quarter.

E Melnyk Failed to Disclose his Full Biovail Share Ownership

148. As a holder of greater than 5% of Biovail's outstanding shares, Melnyk was under a legal obligation to make certain public disclosures concerning his stock ownership under Section 13(d) of the Exchange Act and related rules. On September 23, 1996, Melnyk settled four Cayman Island trusts and funded the trusts with Biovail shares that were previously held by him personally, directly or indirectly. The Biovail shares transferred to the trusts represented approximately 19% of the outstanding shares of Biovail at that time. Melnyk continued to exercise control over the Biovail shares in the trusts. Nevertheless, he did not include in his

public filings pursuant to Section 13(d) of the Exchange Act and related rules any mention of his beneficial ownership of the Biovail shares in the trusts.

Melnyk Had a Beneficial Interest in the Shares Held in the Trusts

149. By 2003, the four trusts' holdings constituted just under eight percent of the Biovail common shares outstanding and approximately 30 percent of Melnyk's total Biovail holdings. Each of the four trusts had a "protector."

150. The controller of Biovail's Barbados subsidiary was separately paid by Melnyk to assist him with issues concerning the trusts, and assumed the role of protector of one of the trusts beginning in 2002. She also was a liaison between Melnyk and the trustees of all four trusts as well as the account representatives on the trusts' brokerage accounts. She conferred with Melnyk regularly about the trusts, including their transactions in Biovail securities.

151. Although the trust documents provide that trustees and the protective committees have investment power over trust assets, including the Biovail shares, Melnyk continued to make decisions concerning both the trusts and the shares they held.

152. Melnyk decided where the brokerage accounts for the trusts would be held – and hence where the Biovail stock would be held – and how that Biovail stock would be voted in Company elections. Melnyk similarly directed when and how the trusts would buy and sell Biovail stock.

153. In addition, Melnyk caused the trustees to sell Biovail stock to fund over $100 million in loans to him from the trusts that he has never repaid. Melnyk knew or should have known that his requests for loans in certain circumstances could reasonably be expected to trigger sales by the trusts of Biovail securities.

154. Melnyk was aware of trading by the trusts in Biovail securities and he could, as a practical matter, exercise control over it and could have stopped it if he wished.

Melnyk Did Not Disclose His Ownership of the Trust Shares in any of his Filings Pursuant to Section 13(d) of the Exchange Act

155. As beneficial owner of more than 5% of the Biovail shares outstanding, Melnyk filed his first Schedule 13-D with the Commission on March 30, 1994. He has since filed twenty three amended Schedules 13-D through January 17, 2007. In none of these filings did he disclose his beneficial interest in the Biovail shares held by the trusts, or any material increases or decreases in the trusts' holdings.

F. Biovail's Violations of Rule 302(b) of Regulation S-T

156. Biovail electronically filed with the Commission certain annual reports on Forms 20-F. The Commission staff requested the Company to furnish to the staff manually signed signature pages or other documents in which the signatories to such electronic filings acknowledged or otherwise adopted their signatures that appear in typed form within the electronic filings. The Company has not complied with that request and is unable to do so.

FIRST CLAIM FOR RELIEF
Violations of Section 17(a) of the Securities Act

157. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 156.

158. Crombie and Biovail, directly or indirectly, singly or in concert, in the offer and sale of securities, by the use of the means and instruments of transportation and communication in interstate commerce or by the use of the mails, directly and indirectly, have employed or are employing devices, schemes and artifices to defraud.

159. Crombie and Biovail, singly or in concert, in the offer and sale of securities, by the use of the means and instruments of transportation and communication in interstate commerce or by the use of the mails, directly and indirectly, have obtained or are obtaining money and property by means of untrue statements of material fact or omissions to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, and have engaged or are engaging in transactions, practices or courses of business which have operated or would operate as a fraud and deceit upon investors.

160. Crombie and Biovail, directly or indirectly, singly or in concert, in the offer and sale of securities described herein, have made untrue statements of material fact, or have omitted to state material facts. Among other things, the materially misleading statements or omissions pertained to Pharmatech's expenses and liabilities related to the research and development of certain Biovail products that Crombie and Biovail intentionally did not include on Biovail's interim financial statements for the period ended September 30, 2001, which Biovail incorporated by reference into the prospectus supplement dated November 15, 2001.

161. Crombie and Biovail knew or were reckless in not knowing of the activities described above.

162. By reason of the foregoing, Crombie and Biovail have violated, and unless enjoined will again violate, Section 17(a) of the Securities Act [15 U.S.C. § 77q(a)].

SECOND CLAIM FOR RELIEF
Violations of and Aiding and Abetting Violations of Section 10(b) of the Exchange Act and Rule 10b-5

163. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 162.

164. Defendants, singly or in concert, in connection with the purchase and sale of securities, directly or indirectly, by the use of the means and instrumentalities of interstate commerce or of the mails, have employed or are employing devices, schemes and artifices to defraud; have made or are making untrue statements of material fact and have omitted or are omitting to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and have engaged or are engaging in acts, practices and courses of business which have operated or would operate as a fraud and deceit upon investors, in violation of Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 [17 C.F.R. § 240.10b-5].

165. Defendants knew or were reckless in not knowing of the activities described above.

166. By reason of the foregoing, Defendants have violated, and unless enjoined will again violate, Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 [17 C.F.R. § 240.10b-5)].

167. By reason of the foregoing, Melnyk, Crombie, Miszuk, and Howling aided and abetted Biovail's violations of, and unless enjoined will again aid and abet violations of, Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 [17 C.F.R. §240.10b-5].

THIRD CLAIM FOR RELIEF
Violations of Section 13(b)(5) of the Exchange Act

168. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 167.

169. Crombie and Miszuk, directly or indirectly, singly or in concert, knowingly circumvented or knowingly failed to implement a system of internal accounting controls and knowingly falsified, directly or indirectly, or caused to be falsified books, records and accounts of Biovail that were subject to Section 13(b)(2)(A) of the Exchange Act [15 U.S.C. § 78m(b)(2)(A)].

170. By reason of the foregoing, Crombie and Miszuk have violated, and unless enjoined will again violate, Section 13(b)(5) of the Exchange Act [15 U.S.C. § 78m(b)(5)].

FOURTH CLAIM FOR RELIEF
Violations of Rule 13b2-1 of the Exchange Act

171. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 170.

172. Crombie and Miszuk, directly or indirectly, singly or in concert, falsified or caused to be falsified the books, records, and accounts of Biovail that were subject to Section 13(b)(2)(A) of the Exchange Act [15 U.S.C. § 78m(b)(2)(A)].

173. By reason of the foregoing, Crombie and Miszuk have violated, and unless enjoined will again violate, Rule 13b2-1 of the Exchange Act [17 C.F.R. § 240.13b2-1].

FIFTH CLAIM FOR RELIEF
Violations of Rule 13b2-2 of the Exchange Act

174. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 173.

175. Crombie and Miszuk were officers of Biovail at all relevant times.

176. As described above, Crombie and Miszuk, directly or indirectly, singly or in concert, made or caused to be made materially false or misleading statements, or omitted to state or caused another person to omit to state material facts necessary in order to make the statements made, in light of the circumstances under which such statements were made, not misleading to an accountant, in connection with (i) audits, reviews and examinations of the financial statements of Biovail required to be made pursuant to Commission regulations, and (ii) the preparation and filing by Biovail of documents and reports required to be filed with the Commission.

177. By reason of the foregoing, Crombie and Miszuk have violated, and unless enjoined will again violate, Exchange Act Rule 13b2-2 [17 C.F.R. § 240.13b2-2].

SIXTH CLAIM FOR RELIEF
Violations of and Aiding and Abetting Violations of Section 13(a) of the Exchange Act and Rules 12b-20, 13a-1, and 13a-16

178. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 177.

179. Biovail did not file with the Commission such financial reports as the Commission has prescribed, and Biovail did not include, in addition to the information expressly required to be stated in such reports, such further material information as was necessary to make the statements made therein, in light of the circumstances in which they were made, not

misleading, in violation of Section 13(a) and of the Exchange Act [15 U.S.C. § 78m(a)] and Rules 12b-20, 13a-1, and 13a-16 [17 C.F.R. §§ 240.12b-20, 240.13a-1, and 240.13a-16].

180. By reason of the foregoing, Biovail violated, and Crombie and Miszuk have aided and abetted Biovail's violations of, Section 13(a) of the Exchange Act [15 U.S.C. § 78m(a)] and Rules 12b-20, 13a-1, and 13a-16 [17 C.F.R. §§ 240.12b-20, 240.13a-1, and 240.13a-16].

SEVENTH CLAIM FOR RELIEF
Violations of and Aiding and Abetting Violations of Sections 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act

181. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 180.

182. Biovail did not:

a. make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflected the transactions and dispositions of its assets; and

b. devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that:

i. transactions were executed in accordance with management's general or specific authorization;

ii. transactions were recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and to maintain accountability for assets;

iii. access to assets was permitted only in accordance with management's general or specific authorization; and

iv. the recorded accountability for assets was compared with the existing assets at reasonable intervals and appropriate action was taken with respect to any differences, in violation of Sections 13(b)(2)(A) and 13(B)(2)(B) of the Exchange Act [15 U.S.C. §§ 78m(b)(2)(A) and 78m(b)(2)(B)].

183. By reason of the foregoing, Biovail violated, and Crombie and Miszuk have aided and abetted Biovail's violations of, Sections 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act [15 U.S.C. §§ 78m(b)(2)(A) and 78m(b)(2)(B)].

EIGHTH CLAIM FOR RELIEF
Violations of Rule 13a-14

184. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 183.

185. Crombie knew or recklessly disregarded that his certifications of Biovail's 2002 and 2003 Forms 20-F were materially false and misleading.

186. By reason of the foregoing, Crombie has violated, and unless enjoined will again violate, Rule 13a-14 [17 C.F.R. § 240.13a-14].

NINTH CLAIM FOR RELIEF
Violations of Section 13(d) of the Exchange Act and Rules 13d-1 and 13d-2

187. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 186.

188. The common stock of Biovail at all relevant times was registered pursuant to Section 12 of the Exchange Act [15 U.S.C. § 78l].

189. Pursuant to Section 13(d) of the Exchange Act [15 U.S.C. § 78m(d)] and Rules 13d-1 and 13d-2 [17 C.F.R. §§ 240.13d-1 and 240.13d-2], persons who are directly or indirectly the beneficial owners of more than five percent of the outstanding shares of a class of voting equity securities registered under the Exchange Act are required to file a Schedule 13D within ten days of the date on which their ownership exceeds five percent, and to notify the issuer and the Commission of any material increases or decreases in the percentage of beneficial ownership by filing an amended Schedule 13D. The Schedule 13D filing requirement applies both to individuals and to two or more persons who act as a group for the purpose of acquiring, holding, or disposing of securities of an issuer.

190. As described above, Melnyk was at all relevant times a beneficial owner of more than 5 percent of Biovail's shares. In addition to the shares that he held in his own name, as a result of his investment and voting authority over the shares held in the trusts, he also was a beneficial owner of those Biovail shares.

191. Melnyk and the trusts also were sufficiently interrelated that they constituted a group for the purposes of the Section 13(d) and the Schedule 13D filing requirement.

192. Accordingly, Melnyk was under an obligation to file with the Commission true and accurate reports with respect to his ownership of the Biovail shares held by the trusts and any material increases or decreases in the percentage of such ownership, pursuant to Section 13(d) of the Exchange Act [15 U.S.C. § 78m(d)] and Rules 13d-1 and 13d-2 [17 C.F.R. §§ 240.13d-1 and 240.13d-2]. He did not do so.

193. By reason of the foregoing, Melnyk violated and, unless enjoined, will again violate Section 13(d) of the Exchange Act [15 U.S.C. §78m(a)] and Rules 13d-1 and 13d-2 thereunder [17 C.F.R. §§ 240.13d-1 and 240.13d-2].

TENTH CLAIM FOR RELIEF
Violations of Rule 302(b) of Regulation S-T

194. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 193.

195. Biovail did not retain and has not produced to the Commission staff upon request manually signed signature pages or other documents authenticating, acknowledging, or otherwise adopting the signatures that appear in typed form within its electronic filings on Form 20-F.

196. By reason of the foregoing, Biovail has violated, and unless enjoined will again violate, Rule 302(b) of Regulation S-T [17 C.F.R. § 232.302(b)].

PRAYER FOR RELIEF

WHEREFORE, the Commission respectfully requests a Final Judgment:

I.

Permanently enjoining Crombie and Biovail, their agents, servants, employees, and attorneys and all persons in active concert or participation with them who receive actual notice of the injunction by personal service or otherwise, and each of them from future violations of Section 17(a) of the Securities Act [15 U.S.C. § 77q(a)].

II.

Permanently enjoining Melnyk, Crombie, Miszuk, Howling, and Biovail, their agents, servants, employees, and attorneys and all persons in active concert or participation with them who receive actual notice of the injunction by personal service or otherwise, and each of them from future violations of Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5) [17 C.F.R. § 240.10b-5], and Melnyk, Crombie, Miszuk, and Howling from aiding or abetting future violations of Sections 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 [17 C.F.R. § 240.10b-5].

III.

Permanently enjoining Biovail, its agents, servants, employees, and attorneys and all persons in active concert or participation with them who receive actual notice of the injunction by personal service or otherwise, and each of them from future violations of Sections 13(a) and 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act [15 U.S.C. §§ 78m(a) and 78m(b)(2)(A) and 78m(b)(2)(B)] and Rules 12b-20, 13a-1, and 13a-16 [17 C.F.R. §§ 240.12b-20, 240.13a-1 and 240.13a-16] and Rule 302(b) of Regulation S-T [17 C.F.R. § 232.302(b)].

IV.

Permanently enjoining Crombie and Miszuk, their agents, servants, employees, and attorneys and all persons in active concert or participation with them who receive actual notice of the injunction by personal service or otherwise, and each of them from future violations of Section 13(b)(5) of the Exchange Act [15 U.S.C. § 78m(5)] and Rules 13b2-1 and 13b2-2 [17 C.F.R. §§ 240.13b2-1 and 240.13b2-2], and from aiding and abetting future violations of Sections 13(a) and 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act [15 U.S.C. §§ 78m(a), 78m(b)(2)(A) and 78m(b)(2)(B)] and Rules 12b-20, 13a-1, and 13a-16 [17 C.F.R. §§ 240.12b-20, 240.13a-1 and 240.13a-16].

V.

Permanently enjoining Crombie, his agents, servants, employees, and attorneys and all persons in active concert or participation with him who receive actual notice of the injunction by personal service or otherwise, and each of them from future violations of Rule 13a-14 of the Exchange Act [17 C.F.R. § 240.13a-14].

VI.

Permanently enjoining Melnyk, his agents, servants, employees, and attorneys and all persons in active concert or participation with him who receive actual notice of the injunction by personal service or otherwise, and each of them from future violations of Section 13(d) of the Exchange Act [15 U.S.C. § 78m(d)] and Rules 13d-1 and 13d-2 [17 C.F.R. §§ 240.13d-1 and 240.13d-2].

VII.

Ordering Biovail, Melnyk, Crombie, Miszuk, and Howling to disgorge any ill-gotten gains from the conduct alleged herein and to pay prejudgment interest thereon.

VIII.

Imposing civil penalties upon Biovail and Crombie pursuant to Section 20(d) of the Securities Act [15 U.S.C. § 77t(d)] and upon Biovail, Melnyk, Crombie, Miszuk, and Howling pursuant to Section 21(d)(3) of the Exchange Act [15 U.S.C. § 78u(d)(3)].

IX.

Permanently barring Crombie, pursuant to Section 20(e) of the Securities Act [15 U.S.C. § 77t(e)], and Melnyk, Crombie, Miszuk, and Howling, pursuant to Section 21(d)(2) of the Exchange Act [15 U.S.C. § 78u(d)(2)], from serving as an officer or director of any issuer that has a class of securities registered under Section 12 of the Exchange Act [15 U.S.C. § 78l] or that is required to file reports pursuant to Section 15(d) of the Exchange Act [15 U.S.C. § 78o(d)].

X.

Granting such other and further relief as to this Court seems just and proper.

Dated: New York, New York
July 31, 2008

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PRODUCT DEVELOPMENT and ROYALTY AGREEMENT

THIS PRODUCT DEVELOPMENT AGREEMENT is made effective the day of June, 2001, between:

BIOVAIL LABORATORIES INCORPORATED.
a Barbados corporation incorporated under the
International Business Companies Act, 1991-24,
whose head office is Chelston Park
Building 2, Collymore Rock
St Michael BH1
Barbados, West Indies

(hereinafter referred to as "BLI")

- and -

PHARMACEUTICAL TECHNOLOGIES CORPORATION.
a company incorporated under the laws of Barbados
whose head office is
c o Chancery Chambers
Chancery House, High Street,
Bridgetown, Barbados
West Indies

(hereinafter referred to as "PTL")

WHEREAS:

BLI is part of a fully integrated international pharmaceutical organization applying advanced drug delivery technologies to the development of medications for the treatment of chronic medical conditions; and

BLI is in the process of developing certain pharmaceutical formulations and wishes to transfer the continued development of those formulations to PTL; and

PTL is a company established for the purpose of contributing to and participating in the development and commercialization of pharmaceutical and drug delivery products, including controlled release and rapid dissolve ("FlashDose™") medicines, and to facilitate the introduction of such products into the pharmaceutical market; and

BLI has agreed to grant to PTL a license to use the FD Technology and the CR Technology on the terms and conditions of, and limitations subject to the of this Agreement to complete the Development of the Products:

PTL has agreed to complete the Development of the Products using the FD Technology and the CR Technology in exchange for the Royalties and other consideration specified in this Agreement.

1. DEFINITIONS

In this Agreement the following definitions shall apply:

1.1 **Advisory Agreement** means the Advisory Agreement effective as of the date hereof between BLI and PTL, pursuant to which BLI has agreed to provide certain services to PTL as PTL may from time to time request.

1.2 **Affiliated Company** means any company that is Controlled directly or indirectly by one of the parties, or any company that directly or indirectly Controls one of the parties, or any company that is directly or indirectly Controlled by a company which also directly or indirectly Controls one of the parties, so that Affiliated Company shall include any parent or subsidiary of one of the parties, or any direct or indirectly held subsidiary of one of the parties. Affiliate has a corresponding meaning.

1.3 **Agreement** means this agreement, all schedules to this agreement and all instruments supplemental to this agreement or in amendment or confirmation of this agreement; hereof, hereto and hereunder and similar expressions mean and refer to this agreement and not to any particular article or section; and article, paragraph, or schedule mean and refer to the specified article, paragraph, or schedule of or to this agreement.

1.4 **Application for Regulatory Approval** means an application made to a Regulatory Authority for permission to Market and or Manufacture the Product in any country in which that Regulatory Authority has jurisdiction.

1.5 **Available Funds** means the aggregate amount of funds to be allocated by PTL to complete the Development of the Products, as set out in the Development Budgets.

1.6 **BLI Technology** means the CR Technology and FD Technology to be used in the Development of the Products.

1.7 **Completion Cost** means at any date, the net present value of the costs agreed to be incurred to complete the Development of any Product, as set out in the original Development Budget for that Product attached as Schedule 1.12 to this Agreement, calculated at such date using the methodology and discount rate set out in Schedule 1.7. The Completion Cost of each Product as of the Effective Date is set out in Schedule 1.7.

1.8 **Control** means with respect to any company, the ownership, directly or indirectly, of more than fifty percent (50%) of the voting rights attached to the issued voting shares of

that company, or the ability to elect a majority of the Board of Directors to that company, or the possession of a contractual right to control the activities of that company.

1.9 **CR Technology** means the Know-How and Patent Rights relating to BLI's technology for manufacturing controlled release formulations of pharmaceutical products.

1.10 **Degree of Completion** means at any date, the percentage obtained by dividing the costs that have been incurred up to and including that date in Developing any Product, by the amount of the original Development Budget for that Product attached as Schedule 1.12 to this Agreement.

1.11 **Develop** means to perform all of the work required to be done for any Product to prepare and file an Application for Regulatory Approval for that Product, to prosecute that Application for Regulatory Approval, and to obtain Regulatory Approval for that Product, and includes, without limitation, such animal toxicology studies, formulation development, in vitro and analytical testing, clinical trials and evaluations, including, as appropriate, Phase I, II and III clinical studies, manufacturing scale-up, process validation studies, and such other clinical tests or studies either (x) as BLI may from time to time reasonably deem appropriate under Article 2 for the purposes set out therein, or (y) as PLT may deem appropriate upon any PLT Grant, and **Developed** has a corresponding meaning.

1.12 **Development Budget** means, for each Product, the Original Development Budget, and any changes to that development budget made pursuant to section 2.3.

1.13 **Development Program** means, for each Product, the original development program set out in Schedule 1.13 to this Agreement, and any changes to that development program made pursuant to section 2.3.

1.14 **Directly Competitive Product** means, with respect to any Product, a product containing the same active ingredient, in the same dosage form and presentation as that Product.

1.15 **Effective Date** means the date of this Agreement set out on page 1.

1.16 **FDA** means the Food and Drug Administration of the United States of America or any successor agency.

1.17 **FD Technology** means the Know-How and the Patent Rights relating to BLI's FlashDose™ technology.

1.18 **First Commercial Sale** means, for any Product, the actual first, material value, arm's length sale of that Product by BLI, or an Affiliate or Licensee of BLI, to a third party after the grant of Regulatory Approval for that Product.

1.19 **Know-How** means all scientific, technical, medical and marketing data, information, expertise, trade secrets, manufacturing, mixing and production procedures, technical assistance, and shop rights of BLI, whether generally known to others or not, and relating to any one or more of the Products, or to the processing, preparing, manufacturing, making or testing, or to the registering, use or sale, of any of the Products, developed by or for BLI prior to the Effective Date and developed by PTL after the Effective Date.

1.20 **Licensee** means a Person, including any Affiliate of BLI, licensed by BLI to Manufacture and/or Market the Product.

1.21 **Manufacture** means to process, prepare, make, test, package or label the Product, and Manufacturing and Manufactured have corresponding meanings;

1.22 **Market** means to promote, distribute, test, market, advertise, sell or offer to sell, and Marketing has a corresponding meaning.

1.23 **Net Sales** means the total of all amounts received by BLI or by an Affiliate of BLI, for any Product sold to arm's length Purchasers (excluding sales by BLI to an Affiliate of BLI, respectively for resale to Purchasers but including sales made by any such Affiliate to a Purchaser, and excluding sales of commercially reasonable quantities of samples sold by BLI or an Affiliate of BLI, respectively) net of the following deductions to the extent that such deductions are commercially reasonable:

(a) distributors', wholesalers' or trade discounts or rebates, and rebates paid to customers for distribution services;

(b) price adjustments to customers' inventories to address market price declines;

(c) charge-backs or rebates actually allowed and taken on such sales in such amounts as are customary in the trade and are specifically related to the Products;

(d) duties and taxes on any sale to the extent separately included in the amount billed;

(e) transportation charges separately itemized;

(f) credits for product returns;

(g) other allowances or deductions agreed on with and actually given to Purchasers.

1.24 **Original Development Budget** means, for each product, the Development budget set out in Schedule 1.4 to this Agreement.

1.25 **Party** means either PTL or BLI, and **Parties** means both of them.

1.26 **Patent Rights** means collectively, any patent application or issued patent, including any continuation, divisional, re-issue and re-examination applications, filed by, or issued or granted to BLI or any Affiliate of BLI, or licensed to BLI or any Affiliate of BLI, which describes or claims any Product, any intermediate or process used or useful in Manufacturing any Product, or any use of any Product, including without limitation the patents and patent applications listed in Schedule 1.26.

1.27 **Person** means an individual, partnership, joint venture, trustee, trust, corporation, body corporate, unincorporated organization or other entity or a government, state or agency or political subdivision thereof, and pronouns have a similarly extended meaning.

1.28 **Products** means the formulations of the drug compounds identified in the left hand column of Schedule 1.28 hereto, and **Product** means any one of them.

1.29 **PTL Grant** means the grant to PTL by BLI of the exclusive right to Develop, Manufacture and Market the Products in the Territory pursuant to section 8.1.

1.30 **Purchasers** means any Person other than BLI, BCI, PTL, or their Affiliated Companies, who purchase Products in arm's length transactions.

1.31 **Qualified Developer** means any Person technically and scientifically qualified to Develop a Product, and reasonably acceptable to BLI, but excludes any direct competitor of BLI or of any Affiliate of BLI, unless BLI consents to the Development of that Product by that competitor.

1.32 **Regulatory Approval** means approval to Market pharmaceutical products issued by the applicable government health authority or authorities.

1.33 **Regulatory Authority** means a government health authority or other body having jurisdiction to grant Regulatory Approvals within the Territories.

1.34 **Royalty Rate** means the rate specified in Schedule 5.1.

1.35 **Royalty Value** means, at any date, and with respect to any Product, the net present value of the royalties expected to be paid to PTL in respect of the sales of that Product, calculated at that date using the methodology and discount rate set out in Schedule 1.7. The Royalty Value for each Product as of the Effective Date is set out in Schedule 1.35.

1.36 **Substitute Product** means a product selected by PTL from the list of products in Schedule 1.36, pursuant to section 9.1.

1.37 **Term** means the period of time that this Agreement will remain in force unless earlier terminated in accordance with the provisions of Article 13.

1.38 **Territory** means all countries of the world.

1.39 **Tramadol Option** means the option granted to BLI under section 7.1.

1.40 **Tramadol Value** means, at any date, the greater of:

(a) the excess of the Royalty Value for Tramadol CR over the Completion Cost for Tramadol CR, each calculated at such date using the methodology and discount rate set out in Schedule 1.7; and

(b) twenty five million dollars ($25,000,000.00)

1.41 Words importing the singular include the plural and vice versa and words importing gender include all genders.

1.42 The division of this Agreement into articles, sections and schedules and the insertion of headings are for convenience of reference only and shall not affect the interpretation or construction of this Agreement.

2. DEVELOPMENT OF PRODUCTS

Engagement of PTL

2.1 BLI hereby engages PTL to Develop each of the Products in accordance with the terms of this Agreement. PTL hereby accepts that engagement, and agrees to undertake the Development of each of the Products, in accordance with the Development Program and Development Budget for that Product attached as Schedule 2.1 and in accordance with the terms of this Agreement.

Disclosure of Development to Date

2.2 Within thirty (30) days after the Effective Date, BLI shall disclose to PTL all of Development work done by or on behalf of BLI with respect to each of the Products up to the Effective Date.

Revisions to Development Programs and Budgets

2.3 PTL and BLI shall negotiate in good faith, as soon as reasonably possible after the end of each calendar quarter, any changes or modifications to any Development Program or Development Budget, including, without limitation, the re-allocation of available research and development funds among the Products, that may be reasonably necessary for the Development, Manufacture and Marketing of the Products, as well as any changes or modifications in BLI's relative priorities for the Development of each of the Products.

If the Parties are unable to agree on any such changes or modifications, BLI may, in its sole discretion, determine those changes or modifications as well as the priority to be given to any part of any Development Program.

Implementation of Development Program

2.4 PTL shall carry out the Development of each Product in accordance with the Development Program.

2.5 PTL may, at its own expense, and on at least ten (10) days advance notice to BLI, engage any one or more Qualified Developers on its behalf to carry out all or any part of the Development of any one or more of the Products, provided that each such Qualified Developer enters into an agreement with PTL in the form of the draft agreement attached as Schedule 2.5 hereto or in such other form as BLI may reasonably approve, a copy of which shall be provided to BLI before execution, and further provided that PTL shall remain liable to BLI for the satisfactory performance of the obligations of PTL under this Agreement.

Protocols and Analytical Methods

2.6 PTL shall at the request of BLI, provide to BLI all proposed trial and test protocols, and master batch documentation, in advance for review, comments, and approval by BLI, which approval shall not be unreasonably delayed or withheld. PTL shall develop and validate all necessary analytical methods required to test each Product, and shall disclose those to BLI for review and approval before use, which approval shall not be unreasonably delayed or withheld. BLI may designate any third person to review any such protocol, documentation or method.

2.7 Any method, protocol or master batch documentation required by this Agreement to be delivered to BLI shall be deemed to be approved by BLI upon the expiry of thirty (30) days from the date of delivery to BLI or any third person designated by BLI pursuant to section 2.6, unless BLI has within that thirty (30) days delivered to PTL a notice specifying all of the defects or deficiencies in such method, protocol, or master batch documentation.

Reporting by PTL

2.8 Within 45 days after the end of each calendar quarter, PTL shall provide to BLI a reasonably detailed report setting forth

(a) a summary of the Development work performed hereunder by PTL or any Qualified Developer during that quarter, including the steps taken and to be taken by or on behalf of PTL to Develop each Product, summaries of any tests or studies conducted by or on behalf of PTL since the last such

report was delivered, and a comparison of the progress made in the Development of that Product against the Development Program; and

(b) the status of all Development Programs at the end of that quarter.

2.9 BLI shall review such reports as soon as reasonably practicable and advise PTL of any concerns or suggestions that BLI may have concerning the Development of any one or more of the Products.

Non-Competition

2.10 BLI shall not, during the Term of this Agreement, Develop or Market, or cause any other Person to Develop or Market in the Territory any Directly Competitive Product , and shall not assist, directly or indirectly, any other Person to Develop, Manufacture or Market any Directly Competitive Product, provided, however, that upon the marketing or imminent marketing by any third party of a generic equivalent to a Product BLI may Develop, Manufacture and or Market its own generic version of that Product. The obligations of BLI under this section with respect to any Product shall terminate upon the later of :

(a) the expiry or termination of BLI's obligation to pay royalties in respect of the sale of that Product ; and

(b) the cessation of Marketing of that Product by PTL, or by any person who, directly or indirectly, acquires the right to Market that Product from PTL, following a PTL Grant.

2.11 PTL shall not assist, authorise or permit any Person other than BLI or an Affiliate or Licensee of BLI, or any Qualified Developer, to Develop, Manufacture or Market any Product in the Territory, and shall not itself Manufacture or Market any Product in the Territory, except as expressly permitted by this Agreement or any other agreement between BLI and PTL, or upon any PTL Grant . PTL shall not Develop, Manufacture or Market any Directly Competitive Product, and shall not assist, directly or indirectly, any other Person to Develop, Manufacture or Market any Directly Competitive Product in the Territory.

3. LICENSE UNDER FD TECHNOLOGY AND CR TECHNOLOGY

Grant of License

3.1 Subject to the terms and conditions of this Agreement, BLI hereby grants to PTL and PTL hereby accepts a non-exclusive and non-assignable (other than with the consent in

writing of BLI) right and sub-licence in the Territory to use the FD Technology and the CR Technology to Develop each of the Products.

3.2 Subject to the provisions of section 2.5, the rights granted to PTL by this Agreement include the right to grant to any Qualified Developer, on notice in writing to BLI, a sub-license to use the FD Technology and or the CR Technology to Develop any one or more of the Products, of the same scope as, or of narrower scope than, (except for the right to grant further sub-licenses), the license granted to PTL by this Agreement.

3.3 Nothing herein is intended to give PTL any ownership of, interest in or assignment of any of the FD Technology or CR Technology, except in accordance with the licence and rights granted to PTL by this Agreement. Upon any termination or expiration of this Agreement with respect to any Product, and subject only to any PTL Grant, PTL shall be deemed to have assigned to BLI any equities or other rights which PTL has or alleges to have acquired in the FD Technology and CR Technology embodied in or used in the Development of that Product, and PTL agrees to execute any and such documents as BLI may require to confirm such assignment without payment of any consideration by BLI.

3.4 BLI hereby makes the following representations and warranties to PTL on and as of the Effective Date:

(a) BLI is the owner or licensee of the BLI Technology, has not granted any licenses to Develop, Manufacture or Market the Products to any other Person, and has the right to grant to PTL the rights granted or to be granted by this Agreement;

(b) To the best of BLI's knowledge, the use of BLI Technology to Develop, Manufacture and Market the Products does not infringe any patent or other intellectual property right owned by any other Person, and no claim or litigation is pending of, to the best of BLI's knowledge, threatened in writing against or affecting BLI contesting its right to sell, license or use any such BLI Technology.

4. APPLICATIONS FOR REGULATORY APPROVAL.

4.1 As soon as reasonably possible after completion of the necessary tests and studies for any Product, PTL shall use all reasonable efforts to prepare an Application for Regulatory Approval of that Product in the United States of America, and shall file that Application for Regulatory Approval in the name of BLI. PTL shall be solely responsible for all aspects of the prosecution of that Application for Regulatory Approval, but except in the event of PTL's negligence or wilful disregard of its obligations under this Agreement, shall not be liable or responsible to BLI in the event that any Application for Regulatory

Approval is not approved or if there is any delay (whether foreseen or unforeseen) in obtaining Regulatory Approval of any Product.

4.2 BLI shall provide to PTL such guidance and assistance as PTL may reasonably require in the preparation and prosecution of that Application for Regulatory Approval. A copy of the Application for Regulatory Approval, as filed shall be provided by PTL to BLI promptly after filing.

Costs

4.3 The costs and expenses of the preparation and prosecution of any and all Applications for Regulatory Approval shall be borne solely by PTL.

Correspondence with Regulatory Authorities

4.4 PTL shall keep BLI fully advised of all steps taken by PTL in the prosecution of each Application for Regulatory Approval, and of the progress of each Application for Regulatory Approval. PTL shall provide to BLI regular reports in respect of each such Application for Regulatory Approval undertaken by PTL.

4.5 PTL shall have the right to select (in its reasonable discretion) the order in which Applications for Regulatory Approval for any Product are filed, but shall be guided in its choice by relative priorities of each of the Products, as established or amended under section 2.3 and by the marketing and sales needs of BLI as communicated by BLI to PTL in discussions and consultations between PTL and BLI from time to time.

4.6 PTL shall provide copies of all correspondence with any Regulatory Authority to BLI immediately after such correspondence is sent or received by PTL. PTL shall, working jointly with BLI, prepare all responses to any deficiency letters received from any such Regulatory Authorities. Either Party shall be permitted to send and receive communication from any Regulatory Authority provided a copy of that communication, if written, or a written report of any telephone contact, is immediately prepared and sent to the other Party not later than 24 hours after the contact.

4.7 If as a result of any change to the formulation of, or any process used to Manufacture, any Product, BLI determines that an amendment or supplement to an original Application for Regulatory Approval should be filed, PTL shall provide to BLI, on reasonable notice from and at no cost to BLI, any data or information reasonably available to PTL relating to the proposed change. BLI shall prepare and file, at its own expense, any such amendment or supplement and shall provide copies of all documents filed to PTL.

4.8 During the Term, PTL shall, at the request of BLI on reasonable notice to PTL, give BLI reasonable access to, and the right to use, all such documents, information, data and technology developed pursuant to the terms of this Agreement, to the extent necessary to

enable BLI to exercise its rights under this Agreement, including without limitation, its rights under this Article 4.

5. ROYALTY PAYMENTS

Royalties

5.1 In consideration of the Development of each of the Products by PTL, and subject to the provisions of sections 5.2 and 13.13, BLI shall pay to PTL, a royalty in respect of each Product, calculated on the basis of the Net Sales of that Product in the Territory, as set out in Schedule 5.1.

5.2 BLI may terminate its obligation to pay any and all royalties under section 5.1 and the amounts required by section 5.4 of this Agreement by delivering to PTL at least thirty (30) days in advance of the expiry of any time period set out below, a notice in writing advising PTL of BLI's intention to terminate those obligations and by paying to PTL within fifteen (15) days of that notice the amount specified below:

Date of delivery of notice	Amount
before December 31, 2001	$50,000,000.
between January 1 and June 30, 2002	$75,000,000.
before December 31, 2002	$110,000,000.
between January 1 and June 30, 2003	$120,000,000.
between July 1 and December 31, 2003	$140,000,000.
between January 1 and June 30, 2004	$150,000,000.
between July 1 and December 31, 2004	$160,000,000.
between January 1 and June 30, 2005	$167,500,000.
between July 1 and December 31, 2005	$175,000,000.
between January 1 and June 30, 2006	$185,000,000.
between July 1 and December 31, 2006	$195,000,000.

5.3 If at any time during the Term of this Agreement PTL delivers to BLI a notice under section 13.3 or section 13.6 of this Agreement, and if within thirty (30) days after the date of delivery of that notice BLI delivers to PTL a notice pursuant to section 5.2, section 13.5 or section 13.8 of this Agreement, the notice from BLI to PTL shall be deemed to have been delivered on the date of delivery of the notice from PTL to BLI.

Marketing by Licensee

5.4 If any Product is Marketed in any country in the Territory by a Licensee, BLI shall not be required to pay the royalties required by section 5.1 of this Agreement in respect of the sales of that Product in that country, but shall instead pay to PTL twenty per cent (20%) of all amounts received by BLI from that Licensee in respect of the sales of that Product in that country.

Payment and Reports

5.5 The payments required by sections 5.1, 5.4, 13.4, or 13.7, shall be due and payable within sixty (60) days of the end of each calendar quarter with respect to sales of each of the Products in the three (3) month periods ending on last days of each calendar quarter. Such royalties and other payments shall be paid to PTL, in U.S. dollars, to such bank account as PTL may designate, subject to any requisite exchange controls, or other governmental consent, being obtained. If such consent is not obtained, the royalty shall be paid to such other bank account of PTL or in such other currency (in the equivalent of the amount due in U.S. dollars calculated at the mean of the buy and sell rates of exchange as quoted to BLI by its main banker at the due date for payment or the date of actual payment, whichever is earlier) as may be permitted by such exchange control. BLI shall on payment of royalties submit a written statement summarizing on a country by country basis the accrual of the royalties in question together with a copy of the quotations of the main banker of BLI on the currency rates in question.

5.6 Within sixty (60) days of the end of each calendar quarter, BLI shall send to PTL a statement certified by a financial officer of BLI disclosing the Net Sales of each Product for the just ended calendar quarter, the total amount of the deductions referred to in each of sub-sections (a) through (g) of section 1.23, the amounts received from any Licensee in respect of sales of any Product by that Licensee, and the royalties due to PTL.

5.7 BLI, if required so to do by any applicable tax law, may deduct any governmental withholding tax required to be deducted by it on payment of royalties hereunder but shall account to the relevant tax authorities for the sum so deducted and provide PTL with proof of such payment from such authorities. BLI shall provide reasonable assistance to PTL in securing any benefits available to PTL with respect to governmental tax withholdings by any relevant law or double tax treaty.

5.8 BLI shall keep at its registered office, and shall cause its Affiliated Companies and Licensees to keep, full and accurate records of the sales of each of the Products for each country for purposes of compliance with its obligations hereunder. Such records shall be made available following the First Commercial Sale of the Product in the Territory, for inspection by PTL or an independent certified public or chartered accountant of PTL's choice during normal business hours after reasonable notice, up to two (2) years after the termination or expiration of this Agreement, and at PTL's expense. Such inspection shall occur no more often than once a year for any Product.

6. TECHNOLOGY TRANSFER

Transfer of Manufacturing Information and Technology

6.1 PTL shall, within thirty (30) days after the conclusion of the Development Program for each Product, disclose to BLI all Know-How, manufacturing information and other data and information in the possession or control of PTL that may assist BLI, or any Affiliate or Licensee of BLI in Manufacturing or Marketing that Product, including without limitation:

(a) all Manufacturing procedures and processes, raw material lists and specifications, equipment lists and specifications for that Product;

(b) master formula describing quantitative composition of all active and inactive components of that Product;

(c) all in vitro test methodologies, test results and product specifications generated by or on behalf of PTL;

(d) all reports of stability studies conducted by or on behalf of PTL; and

(e) all other data and information reasonably required by or useful to BLI in the Manufacture or Marketing of the Product.

6.2 In fulfilment of the obligations of PTL under section 6.1:

(a) technical personnel of BLI shall, at BLI's expense, have the right by prior arrangement to visit any relevant research, development and production facilities of PTL or of any Qualified Developer, to review, examine and acquire any Know-How available that BLI is entitled to have under this Agreement. PTL shall co-operate fully with and assist and shall cause any Qualified Developer to co-operate fully with and assist BLI's personnel in order to facilitate the review, examination and acquisition of that Know-How; and

(b) at the request of BLI, one or more employees of PTL or of the Qualified Developer, knowledgeable in the Manufacture of the Product shall visit the manufacturing facility of BLI or its Licensee to advise and assist BLI's personnel in the use or application of the Know-How to the Manufacture of the Product, and in any relevant analytical and quality control procedures known to PTL or to that Qualified Developer and methods for such Manufacture. Dates and times for such visits shall be arranged at the mutual convenience of BLI and PTL, but shall not be unreasonably delayed by PTL or by the Qualified Developer.

6.3 BLI shall be entitled to a maximum of fourteen (14) person-days of visits referred to in section 6.2 by such employees of PTL or of the Qualified Developer for each Product. Should BLI require additional assistance, PTL shall at the request of BLI provide such assistance, and BLI shall pay to PTL a reasonable per *diem* consulting fee, as agreed to by PTL and BLI in advance, and shall reimburse PTL for the out-of-pocket expenses reasonably incurred by employees of PTL or such Qualified Developer in providing such assistance to BLI.

6.4 PTL shall provide to BLI, and shall cause any Qualified Developer to provide to BLI, any other information relating to each Product as it may possess, including all data and information generated or developed during the Development Program which may be reasonably necessary to enable BLI to Manufacture the Product, within thirty (30) working days of the acquisition or development of such other information.

7. TRAMADOL OPTION

7.1 BLI shall have the right, in its sole discretion, to terminate the Development of Tramadol CR by PTL under this Agreement. BLI may exercise such right by providing thirty (30) days written notice thereof to PTL.

7.2 Within thirty (30) days after the exercise of the Tramadol CR Option, BLI shall pay to PTL the Tramadol Value.

7.3 In the event that BLI exercises the Tramadol Option, BLI shall be entitled to complete the Development of Tramadol CR, and to Manufacture and Market Tramadol CR in the Territory, or to authorize any other person to do so, without further obligation to PTL, and in particular with no obligation to pay any of the royalties required by this Agreement in respect of the sales of Tramadol CR.

7.4 At any time prior to exercise of the Tramadol Option, either BLI or PTL may by notice in writing require the other party to negotiate in good faith the amendment of this Article 7 to replace the option granted with respect to Tramadol CR with an option to terminate the

Development of some other Product by PTL. Upon delivery of that notice, BLI and PTL shall enter into good faith negotiations to agree on:

(a) the Product to be substituted for Tramadol CR for the purposes of this Article 7, and

(b) the amount to be paid on the exercise of that option, which shall not be less than twenty five million dollars ($25,000,000.); and

(c) any other changes to be made to this Agreement consistent with that substitution.

Upon that agreement, and notwithstanding the exercise of the new option, PTL shall continue the development of Tramadol CR, and the Tramadol Option shall no longer be effective.

8. REVERSION OF RIGHTS TO PTL

Failure of BLI to Continue Development

8.1 PTL may at any time after the third anniversary of the Effective Date, by notice in writing to BLI, require BLI to grant to PTL the exclusive license and right to Develop, Manufacture and Market the Products in the Territory provided that:

(a) PTL has spent or has paid to one or more Qualified Developers the aggregate of all of the research and development funds allocated in the Original Development Budgets, as amended pursant to section 2.3 as to the allocation, but without increase in the aggregate amount of the Original Development Budgets, for all of the Products on the Development of the Products; and

(b) the total number of Products that BLI or any Affiliate or Licensee of BLI is Marketing in the Territory, and is Developing on a commercially reasonable basis, as demonstrated by BLI's internal research and development budgets, is less than two.

8.2 The right granted to PTL by section 8.1 shall not apply to any Product that is, at the date of the notice referred to in section 8.1, being Marketed in the Territory by BLI or any Affiliate or Licensee of BLI.

8.3 Provided that it is then commercially reasonable to do so, BLI shall Market or shall cause a Licensee to Market each of the Products in each country in the Territory, within twelve (12) months after the receipt of Regulatory Approval for that Product in each such

country. In addition to the rights granted by section 8.1 of this Agreement, If BLI has not commenced the Marketing of any Product in any such country within twelve (12) months after the receipt of Regulatory Approval for that Product in that country, PTL may notify BLI in writing of the intention of PTL to Market that Product in that country. If BLI has neither Marketed nor caused a Licensee to Market that Product in that country, within six (6) months of the receipt of such notice, BLI shall grant to PTL the exclusive right to Market or authorize others to Market that Product in that country. PTL shall within twelve (12) months after such grant Market the Product in that country, or enter into a license agreement for that Product in that country requiring the licensee to Market that Product within a reasonable period of time. If PTL fails to Market that Product or enter into such a license agreement within the time specified in section 8.3, the rights to PTL to Market the Product in that country shall terminate.

8.4 If PTL acquires the right to Manufacture and Market any Product pursuant to the provisions of sections 8.1 or 8.3 of this Agreement, PTL shall pay, or cause any assignee or licensee to pay, to BLI a royalty of [redacted] of the net sales of any such Product, calculated in the manner prescribed by section 1.23 of this Agreement as if BLI had made such sales.

9. SUBSTITUTION RIGHTS

Development Economics

9.1 PTL may, at any time before BLI or any Licensee of BLI has commenced to Market at least one of the Products by notice in writing to BLI, terminate the Development of all, and only all, of the Products, and advise BLI of PTL's intention to select up to two Substitute Products to be Developed by PTL under the terms of this Agreement:

(a) provided that PTL, acting reasonably and in good faith, shall have determined that the sum of the Royalty Values for all of the Products is less than the sum of the Completion Costs for all of the Products, or

(b) provided that :

i) PTL shall have failed, despite its compliance with the terms of this Agreement and its good faith efforts, to file an Application for Regulatory Approval for at least one of the Products within two (2) years after the Effective Date; and

ii) BLI shall have failed to Market, within three (3) years after the Effective Date, by itself or through an Affiliate or a Licensee, at least one of the Products within twelve (12) months after the granting of Regulatory Approval for that Product in the USA.

9.2 The right granted by section 9.1 may be exercised only once.

9.3 Upon the exercise of the right granted by section 9.1, the Substitute Products shall be Products for all purposes of this Agreement, and BLI and PTL shall cooperate in good faith to prepare Development Budgets and Development Programs for such Substitute Products.

10. CONFIDENTIALITY; ACCESS TO INFORMATION

Obligations of Confidentiality

10.1 During the term of this Agreement and for a period of ten (10) years following its termination, PTL shall maintain in confidence and shall require any Qualified Developer to maintain in confidence and shall not disclose to any other person, except as permitted by this Agreement, or by any other agreement between BLI and PTL, any of the BLI Technology, and shall use such BLI Technology only to perform its continuing obligations under this Agreement or following its termination, unless or except to the extent that the BLI Technology:

(a) was known to or used by PTL prior to its development or disclosure under this Agreement or any other agreement between the parties;

(b) is lawfully disclosed to PTL by a third party unaffiliated with PTL having the right to disclose that technology; or

(c) either before or after the time of disclosure to PTL, such technology becomes known to the public other than by an act or omission of PTL, of any Qualified Developer engaged by PTL, or of their respective employees or agents, not authorized by BLI;

(d) is disclosed to any third party, including any Qualified Developer, upon any PTL Grant, to enable PTL to Develop, Manufacture and Market the Products in the Territory, or to sell, assign, or otherwise exploit the Products, and the rights to the Products, as provided in this Agreement, subject only to the agreement of such third party to respect the confidentiality requirements of this Agreement, and to use the information solely for the purposes set out herein.

Exceptions

10.2 Nothing contained in paragraph 10.1 shall prevent PTL, or any Qualified Developer acting on behalf of PTL, from disclosing any BLI Technology to the extent that such BLI Technology is required to be disclosed

(a) in connection with the securing of necessary Regulatory Approval for the testing or marketing of Products;

(b) by law for the purpose of complying with governmental regulations;

(c) in connection with any license or sublicense permitted under this Agreement, provided that any person to whom the BLI Technology is to be disclosed has executed a confidentiality agreement in a form acceptable to BLI; or

(d) as may be required by applicable laws, regulations, or judicial determinations.

Survival

10.3 The obligations of the parties pursuant to this section 10 shall survive the termination of this Agreement for any reason.

11. PATENTS AND INTELLECTUAL PROPERTY

Patent Filings

11.1 PTL acknowledges that BLI shall own all of the right, title and interest in any inventions, technology, data, formulations or any other information created, discovered or learned by PTL during the Development of the Products. PTL hereby assigns, and shall cause the any Qualified Developer to assign, to BLI all of right, title and interest of PTL or any Qualified Developer in and to any inventions, technology and Know-How relating to the Products. PTL shall at the request of BLI and at no further cost to BLI, execute all such documents as may be necessary to assign and to vest in BLI or its assignee the entire right, title and interest in any such inventions, technology and Know-How and to enable BLI or its assignee to prepare, file and prosecute applications for and to obtain patents or other forms of intellectual property rights.

11.2 BLI may in its sole discretion, or shall at the direction of PTL after any PTL Grant, cause appropriate applications for patents, and for any inventions relating to any Products developed hereunder which BLI or PTL, following any PTL Grant, reasonably believes to be patentable and technically significant, to be prepared and prosecuted in the United States of America and in any other countries in the Territory in which patent protection appears to be available and effective. All of the costs of preparing, filing, prosecuting and maintaining an l such applications and patents, including the Patent Rights, shall be borne by BLI, except to the extent that any such costs are incurred at the direction of PTL.

12. INDEMNIFICATION

12.1 Subject to section 12.5 below, each Party shall indemnify and hold harmless the other Party and its Affiliates as provided below.

12.2 BLI, together with its successors and assigns, shall indemnify and hold PTL, its shareholders, directors, officers, employees and agents ("PTL Indemnitees") harmless from and against all losses, costs, claims, actions, liabilities, including liability for death or personal injury, and expenses (including reasonable attorneys' fees), incurred by any PTL Indemnitee which result from or arise in connection with:

(a) the breach of any representation, covenant or warranty of BLI contained in this Agreement;

(b) any product liability claim relating to any Product including without limitation, any claim based upon any use of any Product, or any defect in any Product that was Manufactured by, or for, BLI or by an Affiliate or Licensee thereof;

(c) any act or omission of BLI or its officers, directors, employees or agents; or

(d) any claims or allegations by a third party that the Development, Manufacture or Marketing of any Product infringes that third party's intellectual property rights.

except to the extent that any such liability, cost, loss or expense is attributable to the negligent or intentional malfeasance of PTL in connection with the performance of its duties and obligations hereunder.

12.3 PTL, together with its successors and assigns, hereby agrees to indemnify and hold BLI, its shareholders, directors, officers, employees and agents ("BLI Indemnitees") harmless from and against any and all losses, costs, claims, actions, liabilities, including liability for death or personal injury, and expenses (including reasonable attorneys' fees) incurred by a BLI Indemnitee which result from or arise in connection with

(a) the breach by PTL of any representation, covenant or warranty of PTL contained in this Agreement; or

(b) any act or omission of PTL or of PTL's officers, directors, employees or agents; or

except to the extent that any such liability, cost, loss or expense is attributable to the negligent or intentional malfeasance of BLI in connection with the performance of its duties and obligations hereunder.

12.4 In the event that the negligent or intentional malfeasance of either PTL or BLI contributes materially to any liability, cost, loss or expense incurred by the other Party, and otherwise arises from the sale of any Product in the Territory or the duties and obligations to be performed hereunder, then PTL or BLI, as the case may be, shall be responsible for that portion of said liability, cost, loss or expense to which such malfeasance contributed.

Procedure for Indemnification

12.5 Upon receiving notice of any claim or suit under section 12.2, 12.3 or 12.4 above, the indemnified Party shall immediately notify the indemnifying Party and shall allow the indemnifying Party and/or its insurer the opportunity to assume direction and control of any and all third party claims, including without limitation the settlement and complete release thereof at the sole option and cost of the indemnifying Party or its insurer. The indemnified Party agrees to cooperate with the indemnifying Party in the conduct of any negotiations, dispute resolution or litigation of any such claim or suit; and the indemnifying Party shall inform the indemnified Party of the progress of the claim or suit at such time and in such manner as is reasonable under the circumstances.

Insurance

12.6 BLI shall maintain comprehensive general liability insurance, product liability insurance as well as other types of insurance in type and amount considered to be reasonable and prudent given the types of risks involved in the Development, Manufacture and Marketing of the Products. BLI shall maintain such coverage with third party commercial insurance carrier(s), for the Term plus the period of any applicable statutory limitation for the sale of goods in the relevant jurisdiction. BLI shall instruct its insurance carriers providing such coverage to notify PTL in writing of any material change in coverage provided by such policies.

12.7 PTL shall maintain comprehensive general liability insurance, product liability insurance as well as other types of insurance in type and amount considered to be reasonable and prudent given the types of risks involved in the Development, Manufacture and Marketing of the Products. PTL shall maintain such coverage with third party commercial insurance carrier(s), for the Term plus the period of any applicable statutory limitation for the sale of goods in the relevant jurisdiction. PTL shall instruct its insurance carriers providing such coverage to notify BLI in writing of any material change in coverage provided by such policies.

13. TERM AND TERMINATION

13.1 This Agreement shall come into force on the Effective Date and shall remain in effect for so long as any Product is being Developed or Marketed, unless terminated by PTL or BLI in accordance with its terms.

13.2 The Parties' respective obligations under Article 2 (except sections 2.10 and 2.11) hereunder shall terminate upon the expenditure by PTL of all Available Funds, unless otherwise mutually agreed to by the parties hereto.

Primary Election to Terminate Development Program

13.3 Subject to the provisions of section 13.4, PTL may on thirty (30) days notice in writing to BLI, terminate its obligations to continue to Develop all (and only all) of the Products pursuant to this Agreement if:

(a) an Application for Regulatory Approval has not been filed in the United States of America for at least one of the Products within two years from the Effective Date; or

(b) BLI has failed to Market within three (3) years after the Effective Date, by itself or through an Affiliate or a Licensee, at least one of the Products within twelve (12) months after the granting of Regulatory Approval for that Product in the USA; or

(c) PTL has been unable to acquire all of the funds required to complete the Development of the Products in accordance with the Development Programs and the Development Budgets, or PTL is in default under any of its material financing agreements from and after June 30, 2004, and BLI is not willing to provide PTL with, or arrange, financing on commercially reasonable terms and rates; or

(d) Biovail Corporation (the parent company of BLI, hereinafter called "Biovail") is in default under any material term of any material financing agreement; or

(e) there is a change in Control of Biovail.

Trailing Royalties

13.4 If PTL terminates the Development of all of the Products pursuant to any of the provisions of sections 9.1 and 13.3, or if BLI terminates the Development of all of the Products pursuant to the provisions of section 13.12, BLI may continue, or may arrange for any Qualified Developer to continue, the Development of the Products. BLI shall pay

to PTL a royalty on the Net Sales of each Product at a rate determined by multiplying the Royalty Rate by the Degree of Completion of that Product at the date of termination.

13.5 BLI may terminate its obligation to pay the amounts required by section 13.4 of this Agreement by delivering to PTL at least thirty (30) days in advance of any the expiry of any time period set out in section 5.2, a notice in writing advising PTL of BLI's intention to terminate that obligation and by paying to PTL within fifteen (15) days of that notice the sum set out in Schedule 13.5 to this Agreement. If BLI does not elect to terminate its obligation to pay the amounts required by section 13.4 of this Agreement under this section, BLI shall, at the written direction of PTL, use reasonable efforts to locate, and to assist PTL to locate, a Person reasonably acceptable to BLI and to PTL willing to pay to to PTL, within an agreed time, and at no cost to PTL, the sum set out in Schedule 13.5 to this Agreement. Upon payment to PTL of the sum set out in Schedule 13.5 by BLI or by such other Person, all obligations of BLI to pay the amounts required by section 13.4 shall be terminated.

Secondary Election to Terminate Development Program

13.6 PTL may, at its option, on thirty (30) days written notice to BLI, terminate the Development of all of the Products if:

(a) PTL, acting reasonably and in good faith, determines that the sum of the Royalty Value of all of the Products is less than the sum of the Completion Cost of all of the Products, or

(b) PTL, acting reasonably and in good faith, determines that BLI will not have the financial capacity to commercialise the Products upon the completion of PTL's Development of the Products.

Reduced Trailing Royalties

13.7 If PTL terminates this Agreement pursuant to the provisions of section 13.6(a) or section 13.6(b), BLI may continue, or may arrange for any other Qualified Developer to continue, the Development of any of the Products. BLI shall pay to PTL a royalty on the Net Sales of any such Product at a rate determined by multiplying the Royalty Rate by fifty percent (50%) of the Degree of Completion for that Product at the time of termination by PTL.

13.8 BLI may terminate its obligation to pay the amounts required by section 13.7 of this Agreement by delivering to PTL at least thirty (30) days in advance of the expiry of any time period set out in section 5.2, a notice in writing advising PTL of BLI's intention to terminate that obligation and by paying to PTL within fifteen (15) days of that notice fifty per cent (50%) of the sum set out in Schedule 13.8 to this Agreement. If BLI does not

elect to terminate its obligation to pay the amounts required by section 13.7 of this Agreement under this section, BLI shall, at the written direction of PTL, use reasonable efforts to locate, and to assist PTL to locate, a Person reasonably acceptable to BLI and to PTL willing to pay to PTL, within an agreed time, and at no cost to PTL, fifty per cent (50%) of the sum set out in Schedule 13.5 to this Agreement. Upon payment to PTL of fifty per cent (50%) of the sum set out in Schedule 13.5 by BLI or by such other Person, all obligations of BLI to pay the amounts required by section 13.7 shall be terminated.

Notice

13.9 If PTL intends to exercise a right of termination under section 13.3 (c), (d) or (e), PTL shall give BLI thirty (30) days notice in writing of that intention. If BLI delivers to PTL a copy of the notice contemplated by section 3(a) of the Share Option Agreement within that thirty (30) day period, PTL's right to terminate this Agreement under any of sub-sections 13.3 (c), (d) or (e) shall expire, the agreement shall not be terminated and PTL shall have no further right to terminate this Agreement. If the transaction contemplated by the Share Option Agreement is not completed, PTL's notice of termination shall be effective.

13.10 BLI may on thirty (30) days notice in writing to PTC, terminate its right to continue to Develop all (and only all) of the Products pursuant to this Agreement, and all of the obligations of BLI under this Agreement, if PTL is unable to acquire all of the funds required to complete the Development of the Products in accordance with the Development Programs and the Development Budgets, and BLI determines that PTL will not have the financial capacity to complete the Development of the Products.

13.11 If BLI intends to exercise a right of termination under section 13.10, BLI shall give PTL thirty (30) days notice in writing of that intention, and shall within that thirty (30) day period exercise its rights under the Share Option Agreement.

13.12 If at any time during the Term of this Agreement PTL is persistently unable or unwilling to devote its own resources or those of any Qualified Developer to any one or more of the Products in the manner contemplated by this Agreement and in a manner consistent with reasonable commercial practice as determined by BLI, BLI may, upon 60 days' written notice to PTL, and upon PTL's failure to take, or to agree to take, within such period, reasonable steps to remedy such situation, terminate this Agreement with respect to any such Product.

Term for Royalty Payments

13.13 Unless earlier terminated pursuant to the provisions of this Agreement, the obligations of BLI and of any Affiliate of BLI under sections 5.1, 5.4, 13.4 and 13.7 of this Agreement with respect to any Product shall expire on the tenth anniversary of the First Commercial

Sale of that Product in the Territory. BLI shall notify PTL in writing of the date of the First Commercial Sale of each of the Products in the Territory.

14. MISCELLANEOUS

Force Majeure

14.1 Neither party to this Agreement shall be liable for delay in the performance of any of its obligations hereunder if such delay results from causes beyond its reasonable control, including, without limitation, acts of God, fires, strikes, acts of war, or intervention of any government authority, but any such delay or failure shall be remedied by such party as soon as practicable. Any time period or limit specified in this Agreement shall be extended by the length of such delay.

Relationship of the Parties

14.2 Nothing contained in this Agreement is intended or is to be construed to constitute BLI and PTL as partners or joint venturers or employees of the other party. Neither party hereto shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other party or to bind the other party to any contract, agreement or undertaking with any third party.

Counterparts

14.3 This Agreement may be executed in any number of counterparts, each of which when so executed shall be deemed to be an original and all of which when taken together shall constitute this Agreement.

Notices

14.4 Any notice or other communication required or permitted to be given to either party under this Agreement shall be given in writing and shall be delivered by hand or by registered mail, postage prepaid and return receipt requested, or by reputable overnight delivery service or courier, addressed to each party at the following addresses or such other address as may be designated by notice pursuant to this paragraph 14.4:

If to PTL:

Pharmaceutical Technology Corporation
c/o Chancery Chambers
Chancery House, High Street,
Bridgetown, Barbados
West Indies

Attention: Mr Trevor Carmichael
Facsimile: 246-431-0076

If to BLI:

Biovail Laboratories Incorporated
Chelston Park
Building 2, Collymore Rock
St Michael BH1
Barbados, West Indies
Attention: Mr. Eugene Melnyk, President
Facsimile: 246-437-7085

14.5 Any notice or communication given in conformity with section 14.4 shall be deemed to be effective when received by the addressee, if delivered by hand or delivery service or courier, and four days after mailing, if mailed.

Governing Law

14.6 This Agreement shall be governed by and construed in accordance with the laws of Canada and the Province of Ontario.

Severability

14.7 If any provision in this Agreement is deemed to be or becomes invalid, illegal or unenforceable, (i) such provision will be deemed amended to conform to applicable laws so as to be valid and enforceable or, if it cannot be so amended without materially altering the intention of the parties, it will be deleted, and (ii) the validity, legality and enforceability of the remaining provisions of this Agreement shall not be impaired or affected in any way.

Amendments

14.8 No amendment, modification or addition hereto shall be effective or binding on either party unless set forth in writing and executed by a duly authorized representative of both parties.

Waiver

14.9 No waiver of any right under this Agreement shall be deemed effective unless contained in a writing signed by the party charged with such waiver, and no waiver of any breach or failure to perform shall be deemed to be a waiver of any future breach or failure to perform or of any other right arising under this Agreement.

Headings

14.10 The section headings contained in this Agreement are included for convenience only and form no part of the agreement between the parties.

Assignment, Etc.

14.11 Neither party may assign its rights and obligations hereunder without the prior written consent of the other party, which may be contained in any other Agreement between PTL and BLI; (which assignee may then exercise the rights of PTL hereunder) provided, however, that BLI shall have the right to assign such rights and obligations hereunder to any Affiliate of BLI or person or entity with which BLI is merged, consolidated or amalgamated, or which purchases all or substantially all of the assets of BLI.

No Effect on Other Agreements

14.12 No provision of this Agreement shall be construed so as to negate, modify or affect in any way the provisions of any other agreement between the parties unless specifically referred to, and solely to the extent provided, in any such other agreement.

Successors

14.13 This Agreement will ensure to the benefit of and be binding upon the successors of the parties hereto.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement on the date first set forth above.

PHARMACEUTICAL TECHNOLOGIES CORPORATION

By: ____________________
Name:
Title:

By: ____________________
Name:
Title:

BIOVAIL LABORATORIES INCORPORATED

By: ____________________
Name:
Title:

By: ____________________
Name:
Title:

IN WITNESS WHEREOF, the parties hereto have executed this Agreement on the date first set forth above.

PHARMACEUTICAL TECHNOLOGIES CORPORATION

By: _____

Name:

Title:

By: _____

Name: Dr. Trevor Carmichael

Title: Secretary

BIOVAIL LABORATORIES INCORPORATED

By: _____

Name: Eugene Melnyk, President and Chief Executive Officer

Title: Director

By: _____

Name: Arlene Fong

Title: Director

Schedule 1.9 – Completion Cost and Royalty Value

to be completed

Schedule 1.28 – Products :

Product	Current Status	Technology	Indication
Fluoxetine	Scale Up	FD	Depression
Oxycodone	Phase I	FD CR	Pain
Paroxetine	Phase I	FD	Depression and Anxiety
Tramadol	Phase III	CR	Pain
Zolpidem	Phase I	FD CR	Sleep Disorders
Buspirone	Phase III	CR	Anxiety

FD= FlashDose

CR=Controlled Release

Schedule 1.35
Royalty Value

to be completed

Schedule 1.36
Potential Substitute Products

to be completed

Schedule 5.1

ROYALTY RATES

Length of time that rate is in effect for any Product	Royalty Rate
For the first two years after the first commercial sale of the Product	5% of Net Sales
For the 3rd and 4th years following the first commercial sale of the Product	7% of Net Sales
From the 4th anniversary of the first commercial sale of the Product, to the 11th anniversary of that first commercial sale	10% of Net Sales

SCHEDULE 13.5

BUYOUT OF TRAILING ROYALTIES UNDER SECTION 13.5

	Date of exercise	Amount
If Tramadol Option has not been exercised	Before 31 December 01	$47,000,000
	January 1 02 to June 30 02	$70,000,000
	July 1 02 to December 31 02	$96,000,000
	January 1 03 to June 30 03	$118,000,000
	July 1 03 to December 31 03	$139,000,000
	January 1 04 to June 30 04	$150,000,000
If Tramadol Option has been exercised	Before 31 December 01	$22,000,000
	January 1 02 to June 30 02	$42,000,000
	July 1 02 to December 31 02	$60,000,000
	January 1 03 to June 30 03	$80,000,000
	July 1 03 to December 31 03	$100,000,000
	January 1 04 to June 30 04	$125,000,000

Schedule

Assigned Contracts

Buspirone

1. Clinical Study Agreement between South Florida Bioavailablity Clinic and Biovail Technologies dated 14 August 2000. PK study comparing Buspirone Hydrochloride ER against Buspar.
2. Pharmaceutical Research Plus, Inc and Biovail Technologies dated 1 June 2000. Program management of Buspirone studies 004, 005 and 008.
3. Worldwide Clinical Trials, Inc. and Biovail Technologies dated 1 May 2000. Clinical Trial Services Agreement for Clinical Research Organization Services in connection with B99.CTOL.008.BUS P02 (Buspirone).
4. Sponsor Authorization for Subcontracting by Worldwide Clinical Trials and Biovail Laboratories, Inc and SmithKline Beecham. Protocol B99.CT3.004. BUS P02 (Buspirone) dated 16 November 1999.
5. Sponsor Authorization for Subcontracting by Worldwide Clinical Trials and Biovail Laboratories, Inc and SmithKline Beecham. Protocol B99.CT3.005. BUS P02 (Buspirone) dated 16 November 1999.
6. Sponsor Authorization for Subcontracting by Worldwide Clinical Trials and Biovail Laboratories, Inc and Covance. Protocol B99.CT3.004. BUS P02 (Buspirone) dated 1 November 1999.
7. Clinical Trial Services Agreement between Worldwide Clinical Trials, Inc. and Biovail Laboratories Inc. dated 30 September 1999. Dose ranging pilot study on Buspirone hydrochloride ER Study B99.CT2A.001 BUS P02.
8. Consulting agreement between Biovail Corporation International and Worldwide Clinical Trials Inc. dated 10 September 1999. Consulting services for clinical development of Buspirone ER IND Submission.
9. Clinical Trial Services Agreement between Worldwide Clinical Trials, Inc. and Biovail Laboratories Inc. dated 15 October 1999. Clinical Research Organization Services in connection with B99.CT3.004. BUS P02 (Buspirone).
10. Clinical Trial Services Agreement between Worldwide Clinical Trials, Inc. and Biovail Laboratories Inc. dated 15 October 1999. Clinical Research Organization Services in connection with B99.CT3.005. BUS P02 (Buspirone).
11. Agreement between Lab Pharmacological Research International, Inc and Biovail Corporation International dated 16 June 1999. LAB Project number 12-1999-0422, contract number 623 for services relating to a study of Biovail's Buspirone 15mg extended release tablets.
12. Agreement between Lab Pharmacological Research International, Inc and Biovail Corporation International dated 15 June 1999. LAB Project number 12-1999-0423, contract number 624 for services relating to a study of Biovail's Buspirone 10 and 15mg extended release tablets.
13. Investigator Agreement between California Clinical Trials Medical Group and Biovail Laboratories Incorporated dated 29 October 1999. Protocol No. B99-CT2A-001 BUS P02 (Buspirone).
14. SmithKline Beecham Clinical Laboratories and Biovail Laboratories Hold Harmless Agreement dated 18 April 2000. Clinical trial for up to 90mg Buspirone Hydrochloride ER in patients with GAD. Protocol No. BOO.CTOL.008.BUSP02.
15. SmithKline Beecham Clinical Laboratories and Biovail Laboratories Hold Harmless Agreement dated 10 April 2000. Clinical trial for up to 90mg Buspirone Hydrochloride ER in patients with GAD. Protocol No. B99.CT3.005.BUSP02.

16. SmithKline Beecham Clinical Laboratories and Biovail Laboratories Hold Harmless Agreement dated 23 February 2000. Clinical trial for up to 90mg Buspirone Hydrochloride ER in patients with GAD. Protocol No. B99.CT3.004.BUSP02.

Tramadol

17. Letter of Intent between SCIREX Corporation and Biovail Laboratories dated 24 August 2000 Tramadol ER 300mg and 200mg vs Placebo for treatment of lower back pain.
18. Letter of Intent between SCIREX Corporation and Biovail Laboratories dated 24 August 2000. Safety and effective of Tramadol HCl ER in the treatment of non-malignant pain.
19. Letter of Intent between SCIREX Corporation and Biovail Laboratories dated 24 August 2000. Tramadol ER vs Placebo for treatment of osteoarthritis of the knee.
20. Consulting Agreement between Scirex (Dr. Donald Mehlisch and Dr. Najib Babul) and Biovail Corporation International dated 21 September 1999 for the drug development program Tramadol Extended Release.
21. Master Clinical Development Agreement between Scirex and Biovail Corporation dated 29 September 1999 for the clinical development project of Tramadol.
22. Research Agreement between Anapharm Inc. and Biovail Corporation dated 17 September 1999 Tramadol 50 jmg limited food effect study.
23. Research Agreement between Anapharm Inc. and Biovail Corporation dated 15 September 1999. Tramadol 50 and 100mg MD.
24. MDS Harris and Biovail Corporation Clinical Agreement dated 10 August 1999 for the performance of Protocol No. B99-30SK-TRAP03.
25. MDS Harris and Biovail Corporation Revised Clinical Agreement dated 24 August 1999 for the performance of Protocol No. B99-30SK-TRAP03.
26. ClinSites and Biovail Corporation Study Agreement dated 8 July 1999 study of Tramadol HCl ER vs Ultram.
27. Phoenix International Life Sciences and Biovail Corporation Project Agreement dated 3 August 1999 Comparative bioavailability study of Tramadol HCl ER tablets.
28. Scirex and Biovail Laboratories Protocol and Amendment dated 14 March 2001. Protocol No B00.CT3.015 TRA P03 comparison of the efficacy and safety of Tramadol ER and Placebo in the treatment of osteoarthritis of the knee

ORIGINAL
- A FEW LINES WERE INADVERTENTLY INTERCHANGED

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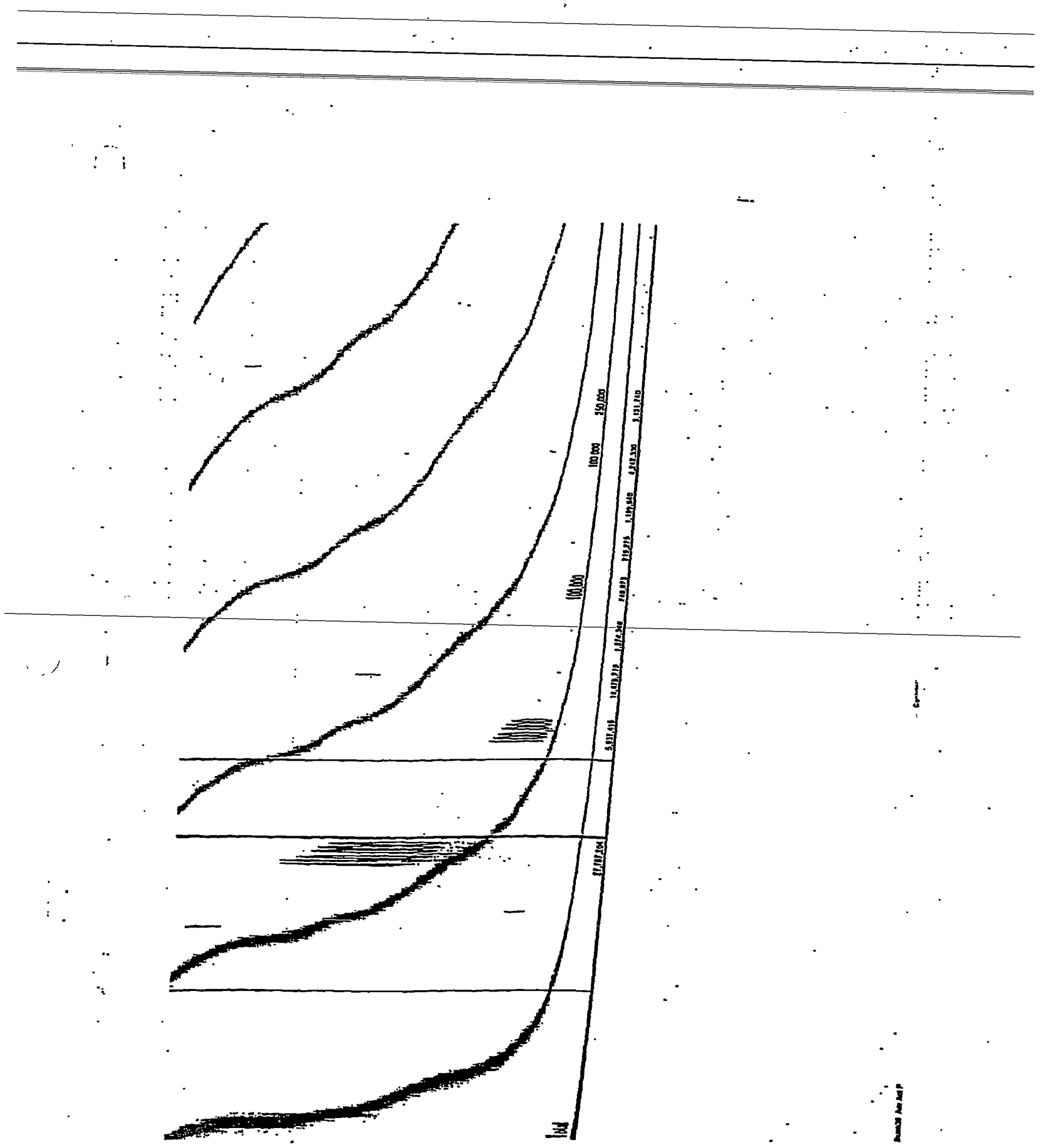
SCHEDULE 1.7

Research & Development Costs remaining

US $ Millions)	Jun-01	Dec-01	Jun-02	Dec-02	Jun-03
Oxycodone	4.3	1.9	0.9	-	
Fluoxetine	19.7	15.3	11.2	7.2	
Paroxetine	5.4	2.5	1.9	1.3	
Zolpidem	35.5	13.3	6.8	0.3	
Tramadol	10.7	7.5	5.3	3.1	
Buspirone	7.9	3.6	1.8	-	
Un Allocated	11.0	11.0	10.5	10.0	
Total	**94.3**	**55.0**	**38.4**	**21.9**	**-**

Note:
-Excludes interest, facility fees, administration and other non R&D costs.
-The above values are not discounted.
-NPV at any date may be calculated using a 25% discount rate.



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Drug: Buspirone
Delivery: Tablet
Strength: 60, 90 mg strengths
Drug Cost per Kg:
Indication: Generalized Anxiety Disorder
Project # : BUS P02 I2
Filing Strategy: NDA 505(b)(2)
Innovator / Brand: BMS Buspar
Technology Partner: Intelipharmaceutics
Contact: Gans

Buspirone 60 and 90 mg

	505(b)(2)												
	Start	Finish	Total Project	97-99	Actuals 2000 Total	Actuals 1Q01	Fcst 2Q01	Fcst 3Q01	Fcst 4Q01	Fcst 2001 Total	2002	2003	2004	2005
Project Startup	Oct-00	Oct-00	-											
Formulation Development	n/a	n/a	-											
Pilot Biostudy	n/a	n/a	-											
Formulation Optimization	n/a	n/a	-											
Second Pilot Biostudy	n/a	n/a	-											
Scale-Up / Process Devel	TBD	TBD	120,000						60,000	60,000	60,000			
Manuf Pivotal Batches/Clinical Supplies	TBD	TBD	60,000						20,000	20,000	20,000	20,000		
Pivotal Biostudy	TBD	TBD	800,000								350,000	450,000		
Stability for Filing	TBD	TBD	-											
Clinical Trials	TBD	TBD	-											
Clinical Supplies			-											
Toxicology	n/a	n/a	-											
Regulatory Submission for Acceptance	TBD	TBD	-											
Approval	TBD	TBD	-											
Estimated Launch			-											
Phase IV Marketing Studies			-											
Milestones			-											
			-											
Total			980,000						80,000	80,000	430,000	470,000		

Buspar60 Ap as

Confid

1:05 PM

Drug:	Fluoxetine HCl
Delivery:	Flash Dose Tablet
Strength:	10, 20, 40 mg
Drug Cost per Kg:	$400/kg
Indication:	Depression
Project # :	FLUNO6 F1
Filing Strategy:	NDA - 505(b)(2)
Innovator / Brand:	Dista / Lilly, Prozac
Technology Partner:	Internal
Champion:	Fogarty / Voelker

Fluoxetine HCl

	505(b)(2) Start	Finish	Total Project	97-99	Actuals 2000 Total	Actuals 1Q01	Fcst 2Q01	Fcst 3Q01	Fcst 4Q01	Fcst 2001 Total	2002	2003	2004	2005
Project Startup	Mar-00	Apr-00	20,000				20,000			20,000				
Formulation Development	Mar-00	Jul-00	86,667		84,067	2,600				2,600				
Pilot Biostudy	May-00	Jun-00												
Formulation Optimization	Apr-01	Apr-01												
Second Pilot Biostudy	n/a	n/a	104,488		104,488									
Scale-Up / Process Devel	Nov-00	Apr-01	52,634			52,634				52,634				
Manuf. Pivotal Batches/Clinical Supplies	Apr-01	May-01	118,000				118,000			118,000				
Pivotal Biostudy	May-01	Oct-01	1,338,894		88,894		250,000	500,000	500,000	1,250,000				
Stability for Filing	May-01	May-02	10,200		10,200									
Clinical Trials	n/a	n/a												
Clinical Supplies														
Toxicology	n/a	n/a												
Regulatory Submission for Acceptance	Nov-01	Jan-02	310,000						310,000	310,000				
Approval	Jan-02	Jan-03												
Estimated Launch	Jan-03													
Phase IV Marketing Studies	TBD	TBD	2,500,000						625,000	625,000	1,875,000			
Milestones														
Total			4,538,881		287,647	55,234	388,000	500,000	1,435,000	2,378,234	1,875,000			

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Drug:	Oxycodone HCl Once Daily
Delivery:	Controlled release tablet or Flash Dose
Strength:	40, 80, 160 mg Dose may be an issue
Drug Cost per Kg:	$5,160
Indication:	chronic pain
Project # :	OXY N05 F1
Filing Strategy:	NDA - 505(b)(2)
Innovator / Brand:	Purdue Pharma / Oxycontin BID
Technology Partner:	Internal and Cima
Champion:	Fogarty / Eradel

Oxycodone HCl

	505(b)(2) Start	Finish	Total Project	12-99	Actuals 2000 Total	Actuals 1Q01	Fcst 2Q01	Fcst 3Q01	Fcst 4Q01	Fcst 2001 Total	2002	2003	2004	2005
Project Startup	Mar-00	Jul-00	-		-					-				
Formulation Development	Aug-00	Jun-01	211,546		211,545	-				-				
Pilot Biostudy	Dec-00	Jul-01	1,601,278		-	231,278	700,000	670,000		1,601,276				
Formulation Optimization	Mar-01	May-01	165,800		-	48,300	82,500	35,000		165,800				
IND Bio Program	Jul-01	Sep-01	800,000		-			800,000		800,000				
Scale-Up / Process Devel	Aug-01	Nov-01	2,000,000		-		1,000,000	1,000,000		2,000,000				
Manuf. Pivotal Batches/Clinical Supplies	Dec-01	Jan-02	275,000		-			-		-	275,000			
Pivotal Biostudy	Jan-02	Jan-03	2,000,000		-			-	-	-	1,800,000	200,000		
Stability	Jan-02	Jan-03	-		-				-	-				
Clinical Trials	Feb-02	Feb-04	13,000,000		-		-		-	-	6,000,000	7,000,000	-	-
Clinical Supplies	-		-		-					-				
Toxicology	n/a	n/a	-		-					-				
Regulatory Submission for Acceptance	Mar-04	May-04	-		-					-				
Approval	May-04	May-05	-		-					-				
Estimated Launch	Nov-05		-		-					-				
Phase IV Marketing Studies	TBD	TBD	-		-					-				
Milestones			-		-					-				
			-											
Total			19,853,821	-	211,545	279,578	1,742,800	2,305,000	-	4,347,078	8,075,000	7,200,000	-	-

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Drug:	Paroxetine HCl
Delivery:	Flash Dose (non-fuse)
Strength:	10,20,30,40mg
Drug Cost per Kg:	$13,500
Indication:	Depression
Project #:	PAR NO FI
Filing Strategy:	NDA - 505(b)(2)
Innovator / Brand:	Smith Kline Beecham - Paxil
Technology Partner:	Internal
Champion:	Frisbee

Paroxetine HCl

	505(b)(2) Start	Finish	Total Project	97-99	Actuals 2000 Total	Actuals 1Q01	Fcst 2Q01	Fcst 3Q01	Fcst 4Q01	Fcst 2001 Total	2002	2003	2004	2005
Project Startup	Apr-00	Jul-00	-		-					-				
Formulation Development	May-00	Nov-00	82,187		82,187					-				
Pilot Biostudy	Nov-00	Feb-01	45,603		36,109	9,494				9,494				
Formulation Optimization	Jan-01	Apr-01	100,422		-	45,422		55,000		100,422				
Second Pilot Biostudy	n/a	n/a	-		-					-				
Scale-Up / Process Devel	Apr-01	Mar-01	900,000		-		500,000	200,000	200,000	900,000				
Manuf. Pivotal Batches/Clinical Supplies	May-01	Jun-01	700,000		-		400,000	300,000		700,000				
Pivotal Biostudy	Jun-01	Dec-01	900,000		-		300,000	300,000	300,000	900,000				
Stability for Filing	Jun-01	Dec-01	-		-					-				
Clinical Trials	n/a	n/a	-		-					-				
Clinical Supplies			-		-					-				
Toxicology	n/a	n/a	-		-					-				
Regulatory Submission for Acceptance	Dec-01	Feb-02	310,000		-				310,000	310,000				
Approval	Feb-02	Feb-03	-		-					-				
Estimated Launch	Aug-04		-		-					-				
Phase IV Marketing Studies	TBD	TBD	2,500,000		-					-		1,250,000	1,250,000	
Milestones			-		-					-				
Total			5,616,182	-	98,276	54,918	1,200,000	855,000	810,000	2,919,918	-	1,250,000	1,250,000	-

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Drug: Tramadol
Delivery: Tablet
Strength: 100, 200 mg
Drug Cost per Kg: $400
Indication: chronic pain
Project #: TRA PO2 P1
Filing Strategy: NDA - 505(b)(2)
Innovator / Brand: McNeil / Ultram
Technology Partner: Pharmapass
Champion: [illegible]

Tramadol 100 and 200

	100 mg Start	100 mg Finish	100 mg Total Project	200 mg Start	200 mg Finish	[illegible]	Actuals 2000 Total	Actuals 1Q01	Fcst 2Q01	Fcst 3Q01	Fcst 4Q01	Fcst 2001 Total	2002	2003	2004	2005
Project Startup	Jan-99	Apr-99	122,874	Jul-00	Jul-00		122,874					-				
Formulation Development	Oct-98	Apr-99	636,601	Jul-00	Sep-00		636,601					-				
Pilot Biostudy	n/a	n/a	646,378	n/a	n/a	646,378	-					-				
Formulation Optimization	May-99	Jul-99	-	n/a	n/a		-					-				
Second Pilot Biostudy	Aug-99	Jan-00	113,305	n/a	n/a		113,305					-				
Scale-Up (Process Devel)	Nov-99	Dec-00	2,441,280	Mar-01	Apr-01	150,000	1,937,473	2,803	300,000			302,806				
Manuf. Pivotal Batches/Clinical Supplies	Feb-00	May-01	100,000	Apr-01	May-01	100,000	-					-				
Pivotal Biostudy	Feb-00	Jun-01	1,128,606	May-01	Feb-02		270,361	6,244	300,000	450,000	100,000	856,244				
Stability for Filing	Apr-00	May-01	4,431	May-01	May-02		4,431					-				
Clinical Trials	Oct-00	Jun-02	28,810,221	n/a	n/a	271,597	3,171,218	751,964	3,022,393	5,518,218	5,528,740	17,821,318	7,845,893			
Clinical Supplies			80,378				30,182	11,142				11,142				
Toxicology	Jun-98	Jun-02	2,652,078	n/a	n/a	1,106,891	385,385	123,876	318,175	318,175	241,175	987,200	188,900			
Regulatory Submission for Acceptance	Jun-02	Sep-02	215,000	Jun-02	Sep-02		-					-	215,000			
Approval	Sep-02	Aug-03	-	Sep-02	Aug-03		-					-				
Estimated Launch	Mar-05		-				-					-				
Phase IV Marketing Studies	TBD	TBD	8,421,028	n/a	n/a		-			175,926	582,814	1,358,740	4,062,288			
Milestones			2,275,000			1,150,000	-		875,000		425,000	1,300,000	575,000	300,000		
			-													
Total			45,362,219			3,324,824	8,860,870	894,830	8,903,768	7,460,319	8,877,728	32,136,648	12,930,879	300,000		

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Drug: Zolpidem Tartrate Flash Dose
Delivery: Flash Dose / Conventional Tablet
Strength: 5, 10 mg
Drug Cost per Kg: $6,500
Indication: Insomnia
Project # : ZOL N04 F1
Filing Strategy: NDA - 505(b)(2)
Innovator / Brand: Searle / Lorex, Ambien
Technology Partner: Internal
Champion: Fogarty

Zolpidem Tartrate Flash Dose

	Flash Dose Start	Flash Dose Finish	Total Project	BT-99	Actuals 2000 Total	Actuals 1Q01	Fcst 2Q01	Fcst 3Q01	Fcst 4Q01	Fcst 2001 Total	2002	2003	2004	2005
Project Startup	Jun-00	Jul-00	-		-					-				
Formulation Development	Jun-00	Sep-00	304,749		304,749					-				
Pilot Biostudy	Sep-00	Nov-00	418,875		131,200	68,375	218,000			286,375				
Formulation Optimization	n/a	n/a	60,000		-	60,000				60,000				
Additional Pilot Biostudy	Feb-01	Apr-01	502,304		167,304		85,000	250,000		335,000				
Scale-Up / Process Devel	Jun-01	Jun-01	1,560,000		-	-	1,170,000		390,000	1,560,000				
Manuf. Pivotal Batches/Clinical Supplies	Jun-01	Jun-01	47,000		-			47,000		47,000				
Pivotal Biostudy	Jun-01	Sep-01	1,300,000		-		200,000	350,000		550,000	750,000			
Stability for Filing	Jun-01	Sep-01	55,820		55,820					-				
Clinical Trials	n/a	n/a	1,750,000		-					-	1,750,000			
Clinical Supplies			-											
Toxicology	n/a	n/a	-		-					-				
Regulatory Submission for Acceptance	Sep-01	Nov-01	310,000		-			310,000		310,000				
Approval	Nov-01	Nov-02	-		-					-				
Estimated Launch	Oct-03		-		-					-				
Phase IV Marketing Studies	TBD	TBD	5,000,000		-					-	1,875,000	3,125,000		
Milestones			-		-					-				
Total			11,302,348	-	658,073	128,375	1,671,000	957,000	390,000	3,142,375	4,375,000	3,125,000	-	-

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SCHEDULE 1.1 -6 pages

Project Name: Buspirone HCl ER	Indication/Purpose: Develop and obtain FDA approval for once-daily solid oral dosage form of Buspirone HCl ER for the management of Generalized Anxiety Disorder (GAD).

Filing: *NDA, 505(b)(2)*

Phase:	Filing date:	Approval Date:	Est. Launch Date:
US III (30mg) I (60 & 90mg)	US TBD	US TBD	US TBD
C Same as US	C TBD	C TBD	C TBD

BUSPIRONE HCl ER 30 mg MILESTONES

	Target		Latest Estimate	
Development Milestones	Start	Completion	Start	Completion
Project Startup	01/98	11/98	01/98	11/98
Formulation Development	06/98	09/98	06/98	04/99
Pilot Biostudy	09/98	12/98	10/98	02/99
Formulation Optimization	N/A	N/A	06/98	10/00
Second Pilot Biostudy	N/A	N/A	06/99	06/00
Scale-up/Manuf. Pivotal & Clinical Supplies	05/99	08/99	08/99	10/00
Stability	10/99	10/00	10/99	02/01
Pivotal Biostudies	08/99	10/99	08/99	12/00
Phase II/III Clinical Studies	12/99	07/00	10/99	12/00
Toxicology Program	02/98	06/02	05/98	01/02
NDA Filing	N/A	12/00	TBD*	TBD
NDA Approval	N/A	12/01	TBD	TBD
Phase IV Marketing Studies	01/01	01/02	TBD	TBD
Estimated Launch Date	–	–	TBD	TBD

** Additional Phase III clinical studies currently being planned.*

BUSPIRONE HCl ER MILESTONES 60, 90 mg, (b)(1) conversion

	Target		Latest Estimate	
Development Milestones	Start	Completion	Start	Completion
Project Start-up	01/98	11/98	10/00	10/00
Formulation Optimization	N/A	N/A	N/A	N/A
Second Pilot Biostudy	N/A	N/A	N/A	N/A
Scale-up/Manuf. Pivotal & Clinical Studies	03/00	04/00	TBD*	TBD
Stability	04/00	11/00	TBD	TBD
Pivotal Biostudies	05/00	08/00	TBD	TBD
Phase III Clinical Studies	12/99	07/00	TBD	TBD
Toxicology Program	02/98	06/02	05/98	01/02
NDA Filing	N/A	12/00	TBD	TBD
NDA Approval	N/A	12/01	TBD	TBD
Phase IV Marketing Studies	N/A	N/A	N/A	N/A
Estimated Launch Date	–	–	TBD	TBD

** Timeline for continuation of 60 & 90mg development currently under assessment.*

Project Name: Fluoxetine FDT	Indication/Purpose: Develop and secure FDA approval for fluss-based Flash Dose tablet, which matches the profile of Prozac® for use in the treatment of depression

Filing: *NDA, 505(b)(2)*

Phase:	Filing date:	Approval Date:	Est. Launch Date:
US II	US 11/01	US 01/03	US 01/03
C Same as US	C Same as US	C 07/03	C 07/03

FLUOXETINE 10, 20 & 40mg FDT MILESTONES

	Target		Latest Estimate	
Development Milestones	Start	Completion	Start	Completion
Formulation Development	01/00	11/00	03/00	07/00
Pilot Biostudies	05/00	11/00	05/00	06/00
Formulation Optimization (Marketing taste assessment of FD)			04/01	04/01
Optimized (2nd) Pilot Biostudy	—	—	N/A*	N/A
Scale-up/Manufacture Pivotal batches	06/00	12/00	11/00	05/01
Stability	12/00	01/02	05/01	05/02
Pivotal Biostudy	12/00	07/01*	05/01	10/01
Phase III Clinical Studies	——	N/A	N/A	N/A
Toxicology Program	——	N/A	N/A	N/A
NDA Filing	07/01	10/01	11/01*	01/02
NDA Approval	——	07/02	01/02	01/03
Phase IV Marketing Studies	N/A	N/A	TBD	TBD
Estimated Launch Date	–	–	01/03	–

** In order to meet timeline for submission, the decision was made to forego further pilot biostudy and to move directly into pivotal biostudy program in order to achieve November 2001 target submission date.*

** File based on 6 months stability data. Target submission date extended by one month to Nov. '01 due to length of pivotal biostudy program (six months from initiation to final report).*

Note: (US submission)—Approval date of 01/03 represents tentative approval date and assumes 14 months from date of submission to approval, which presents worst-case scenario (FDA review cycle time currently averaging 12-14 months). Estimated launch date assumes that we will not be sued by innovator company, since generic market opens in 8/01, and that we can launch immediately after tentative approval is received. (Canadian submission)—Approval date of 07/03 assumes 20 months from date of submission to approval (TPP review cycle time currently averaging 18-20 months).

Project Name:
Paroxetine HCl

Indication/Purpose:
Develop and secure FDA approval for floss-based Flash Dose Tablets to be available in 4 dosages and used in the treatment of depression and anxiety.

Filing: *NDA-505(b)(2)*

Phase:	Filing date:	Approval Date:	Est. Launch Date:
US I	US 12/01	US 02/03	US 08/04
C Same as US	C Same as US	C 08/03	C 08/03

PAROXETINE HCl FLASH DOSE TABLETS 10, 20, 30, 40mg MILESTONES

	Target		Latest Estimate *	
Development Milestones	Start	Completion	Start	Completion
Project Startup	04/00	07/00	04/00	07/00
Formulation Development	04/00	10/00	05/00	11/00
Pilot Biostudy	11/00	02/01	11/00	02/01
Formulation Optimization (Marketing taste assessment for FDA	01/01	02/01	01/01	04/01
Second Pilot Biostudy	02/01	05/01	N/A	N/A
Scale-up/Manuf. Pivotal Batches	02/02	10/02	04/01	06/01
Stability	10/02	11/02	06/01	12/01
Pivotal Biostudies	10/02	04/03	06/01	12/01
Phase I/II/III Clinical Studies	N/A	N/A	N/A	N/A
Toxicology Program	N/A	N/A	N/A	N/A
NDA Filing	05/03	08/03	12/01	02/02
NDA Approval	08/03	05/04	02/02	02/03
Phase IV Marketing Study	N/A	N/A	TBD	TBD
Estimated Launch Date	--	--	08/04	--

** Bold dates denote a Best Case Scenario required in order to achieve the announced filing of December 2001.*

Note: (US submission)—Approval date of 02/03 represents tentative approval date and assumes 14 months from date of submission to approval, which presents worst-case scenario (FDA review cycle time currently averaging 12-14 months). Estimated launch date assumes 30-month litigation clock for 505(b)(2) submission, which starts from time that patent holder is notified of our submission (45 days after filing). The 30-month litigation clock assumes that we file Paragraph IV certification and that we are sued by patent holder. (Canadian submission)—Approval date of 08/03 assumes 20 months from date of submission to approval (TPP review cycle time currently averaging 18-20 months).

Project Name: Oxycodone HCl	Indication/Purpose: Develop a 24-hour profile for an Oxycodone Flash Dose Tablet and/or conventional dosage form for the treatment of pain.

Filing: *NDA, 505(b)(2)*

Phase:	Filing date:	Approval Date:	Est. Launch Date:
US 1	US 03/04	US 05/05	US 11/06
C Same as US	C Same as US	C 11/05	C 11/05

OXYCODONE HCl 20, 40, 80 & 160mg MILESTONES

	Target		Latest Estimate	
Development Milestones	Start	Completion	Start	Completion
Project Startup	03/00	07/00	03/00	07/00
Formulation Development	08/00	06/01	08/00	06/01
Pilot Biostudy	12/00	07/01	12/00 *	07/01
Formulation Optimization (Marketing taste assessment of FD)	03/01	05/01	03/01	05/01
IND Bio Program	02/01	02/01	07/01	09/01**
Scale-up/Manuf. Pivotal Batches	08/01	01/02	08/01	01/02
Stability	01/02	01/03	01/02	01/03
Pivotal Biostudies	01/02	01/03	01/02	01/03
Phase II/III Clinical Studies	02/02	02/03	02/02	02/04***
Toxicology Program	N/A	N/A	N/A	N/A
NDA Filing	01/03	04/03	03/04	05/04
NDA Approval	05/03	03/04	05/04	05/05
Phase IV Marketing Studies	02/02	02/03	TBD	TBD
Estimated Launch Date	–	–	11/06	–

** Pain biostudies conducted with 80mg strength only at this point.*

*** IND Bio Program under review.*

**** Dates provide above for Phase III clinical program are based on availability of clinical product in Jan '02, and duration of studies based on recently received clinical protocols. Clinical protocols length of study based on what we believe to be FDA's requirements for Oxycodone clinical program. As a result of these clinical protocols, the target submission date has been revised to submission date of March '04 (previously March '03).*

Note: (US submission)—Approval date of 5/05 represents tentative approval date and assumes 14 months from date of submission to approval, which presents worst-case scenario (FDA review cycle time currently averaging 12-14 months). Estimated launch date assumes 30-month litigation clock for 505(b)(2) submission, which starts from time that patent holder is notified of our submission (45 days after filing). The 30-month litigation clock assumes that we file Paragraph IV certification and that we are sued by patent holder. (Canadian submission)—Approval date of 11/05 assumes 20 months from date of submission to approval (TPP review cycle time currently averaging 18-20 months).

Additional Project Steps	Start	Finish
File IND	Oct-01	Dec-01
FDA Meeting (pre-IND)	TBD	TBD
Confirmatory Bioavailability Study	Nov-01	Jan-02

Project Name: Tramadol	Indication/Purpose: For the treatment of chronic pain.

Filing: *NDA, 505(b)(2)*

Phase:	Filing date:	Approval Date:	Est. Launch Date:
US II/III	US 06/02	US 08/03	US 03/05
C Same as US	C Same as US	C 02/04	C 02/04

TRAMADOL 100mg MILESTONES

	Target		Latest Estimate	
Development Milestones	Start	Completion	Start	Completion
Project Startup	01/99	06/99	01/99	06/99
Formulation Development	07/99	10/99	10/98	04/99
Formulation Optimization	05/99	07/99	05/99	07/99
Second Pilot Biostudy	08/99	01/00	08/99	01/00
Scale-up/Process Development	11/99	12/00	11/99	12/00
Manufacture Pivotal Batches/ Clinical Supplies	02/00	12/00	02/00	05/01
Stability (12 mos.)	12/99	12/00	04/00	05/01
Pivotal Biostudies	02/00	05/00	02/00	06/01
Phase III Clinical Studies				
- Lower back pain			10/00	09/01
- Osteoarthritic pain			10/00	06/01
- Open label extension			10/00	06/02
Toxicology Program	N/A	N/A	06/98	06/02
NDA Filing	06/02	09/02	06/02	09/02
NDA Approval	09/02	06/03	09/02	08/03
Phase IV Marketing Studies	04/01	04/02	TBD	TBD
Estimated Launch Date (100 & 200mg)	–	–	03/05	–

Note: A pre-NDA meeting with DAAODP will be scheduled for December 2001 or January 2002.

TRAMADOL (PHARMAPASS) 200 mg MILESTONES

	Target		Latest Estimate	
Development Milestones	Start	Completion	Start	Completion
Project Startup	07/00	07/00	07/00	07/00
Formulation Development	07/00	09/00	07/00	09/00
Scale-up/ Process Development	07/00	10/00	03/01*	04/01
Manufacture Pivotal /Clinical Supplies	10/00	12/00	04/01	05/01
Pivotal Biostudies	01/01	12/01	05/01	02/02
Stability for Filing	01/01	01/02	05/01	05/02
Phase III Clinical Studies	N/A	N/A	N/A	N/A
Toxicology Program	N/A	N/A	N/A	N/A
NDA Filing	Same as for the 100mg		06/02	09/02
NDA Approval	Same as for the 100mg		09/02	08/03

**Scale-up of 200mg did not commence as planned in December due to issues with coating equipment. Scale-up of 200mg formulation to be scheduled.*

Note: (US submission)—Approval date of 8/03 represents tentative approval date and assumes 14 months from date of submission to approval, which presents worst-case scenario (FDA review cycle time currently averaging 12-14 months). Estimated launch date assumes 30-month litigation clock for 505(b)(2) submission, which starts from time that patent holder is notified of our submission (45 days after filing). The 30-month litigation clock assumes that we file Paragraph IV certification and that we are sued by patent holder. (Canadian submission)—Approval date of 02/04 assumes 20 months from date of submission to approval (TPP review cycle time currently averaging 18-20 months).

Project Name:
Zolpidem FDT

Indication/Purpose:
Develop a taste-masked microsphere for incorporation into a floss-based rapid dissolve tablet which matches the profile of Ambien for the treatment of insomnia.

Filing: *NDA – 505(b)(2)*

Phase:	Filing date:	Approval Date:	Est. Launch Date:
US 1	US 09/01	US 11/02	US 10/06
C Same as US	C Same as US	C 05/03	C 10/06

Zolpidem Tartrate 5 and 10mg FDT MILESTONES

	Target		Latest Estimate	
Development Milestones	Start	Completion	Start	Completion
Project Startup	06/00	07/00	06/00	07/00
Formulation Development	06/00	09/00	06/00	09/00
Pilot Biostudy	09/00	11/00	09/00	11/00
Formulation Optimization (Marketing taste assessment for FD)	N/A	N/A	06/01	06/01
Second Pilot Biostudy	N/A	N/A	02/01	04/01
Scale-up/Manuf. Pivotal Batches	11/00	05/01	06/01*	06/01
Stability	05/01	05/02	06/01	06/02
Pivotal Biostudies	06/01	11/01	06/01	09/01
Phase II/III Clinical Studies	N/A	N/A	N/A	N/A
Toxicology Program	N/A	N/A	N/A	N/A
NDA Filing	05/02	08/02	09/01	11/01
NDA Approval	08/02	05/03	11/01	11/02
Phase IV Marketing Study	05/02	05/03	TBD	TBD
Estimated Launch Date	–	–	10/06^	–

** Decision made that scale-up will occur in Chomiller license for schedule 4 controlled substance expected in time to support scale-up in June.*

Note: (US submission)—Approval date of 11/02 represents tentative approval date and assumes 14 months from date of submission to approval, which presents worst-case scenario (FDA review cycle time currently averaging 12-14 months). Estimated launch date is based on expiry of active patent. (Canadian submission)—Approval date of 06/04 assumes 20 months from date of submission to approval (TPP review cycle time currently averaging 18-20 months).

^ Patent expiry date is October 2006.

SCHEDULE 1.35

	Dec-01	Jun-02	Dec-02	Jun-03	Dec-03	Jun-04	Dec-04	Jun-05	Dec-05	Jun-06	Dec-06
Discount Rate 25%											
NPV Fututre Royalties											
US $ Millions)											
Oxycodone	47.3	53.2	59.1	66.5	73.9	83.2	92.4	104.0	115.5	129.5	143.4
Fluoxetine	41.9	47.2	52.4	57.7	62.9	67.0	71.0	74.0	76.9	74.6	72.2
Paroxetine	41.3	46.5	51.6	56.1	64.5	72.1	79.7	87.1	94.4	98.2	101.9
Zolpidem	24.5	27.6	30.6	34.5	38.3	43.1	47.9	53.9	59.8	66.1	72.4
Tramadol	18.7	21.0	23.3	26.3	29.2	32.9	36.5	40.3	44.1	48.1	52.0
Buspirone	62.4	70.2	78.0	86.6	95.2	103.2	111.2	114.3	117.3	115.1	112.8

SCHEDULE 1.36

Substitute Products

1 Venlafaxine FD

2 Clarithromycin FD

3 Azithromycin FD

4 Confidential Product
(ref. Page 23 of the Q1 Project Management Report)

ERNST & YOUNG

Ernst & Young LLP
Chartered Accountants
First & Trust Tower
PO Box 251, 222 Bay St
Toronto-Dominion Centre
Toronto, Ontario M5K 1J7

June 29, 2001

PRIVATE AND CONFIDENTIAL

Mr. Brian Crombie
Senior Vice President and Chief Financial Officer
Biovail Corporation
2488 Dunwin Avenue
Mississauga, Ontario
L5L 1J9

Dear Mr. Crombie:

Re: **Biovail Corporation and its subsidiaries ("Biovail") – Accounting Implications of Pharmaceutical Technologies Limited ("PTL")**

We have been engaged to report on the appropriate application of United States generally accepted accounting principles to the transaction described below. This letter is being issued to assist management to evaluate the accounting for the described transaction

Transaction summary

Biovail is proposing to enter into a transaction, described in detail in the Transaction Summary attached as Appendix A, involving research and development to be conducted by PTL in exchange for a royalty interest with respect to a minimum of six of Biovail's current drug development opportunities. This letter is based on copies of draft agreements and other information that were provided to us by management of Biovail up to the date of this letter. If the final versions of the agreements differ from the information provided to us, our current advice with respect to the accounting implications may change.

The most significant terms of the transaction as currently understood by us are summarized below

1. Biovail will not own any debt or equity securities of PTL.
2. All of the share capital of PTL (approximately $1 million) will be owned by an unrelated group of third party investors
3. PTL will continue the development of certain drug applications that had been previously identified by Biovail in return for a royalty interest in revenues that may be earned from the eventual regulatory approval and sale of any of the products included in the arrangement. Most of the products are in the early stages of research and development. Two of the products have reached Phase III clinical trials but development, regulatory and market risks continue to

cause significant uncertainty as to whether these products ultimately will be approved and sold.

4. PTL's right to develop the specified products is exclusive to it while the product development and royalty agreement remains in force.

5. PTL will finance the proposed drug development program from a bank lending facility. The lending facility, which will aggregate approximately $140 million once fully utilized, will be provided in three successive annual tranches of $60 million, $40 million and $30 million respectively, based on the current project development plan. The proposed advances under the credit facility will be subject to annual approval by the lender. The lending facility will carry high interest rates (approximately 23%) reflecting the significant risk associated with the investment.

6. The only security available to PTL's lender will be PTL's royalty interests. However, in order to demonstrate to the lender that Biovail and PTL intend to work together with respect to the product development program, Biovail will provide an undertaking to the lender to not sell its PTL share and royalty options, to assume PTL's debt if the share option is exercised and to not amend the product development and royalty agreement without the lender's consent.

7. Biovail will retain the right but not the obligation to reacquire one of the product development opportunities, Tramadol, being developed by PTL. The option exercise price payable by Biovail is the greater of the estimated net present value of expected future royalties less future development costs or $25 million. Biovail and PTL may also negotiate for the transfer of a product development opportunity other than Tramadol to Biovail but, in any event, only one of the six original products could be transferred under this option arrangement.

8. Biovail will have an option (but not an obligation) to acquire the equity of PTL for various amounts set out in the agreement starting at $1.75 million on December 31, 2002 and increasing to $5 million by December 31, 2006.

9. Biovail will have an option (but not an obligation) to acquire PTL's royalty interests at negotiated amounts beginning at $50 million on December 31, 2001 and increasing to $195 million by December 31, 2006.

10. PTL shareholders and lenders will not have any contractual or constructive right or ability to put PTL's shares or PTL's royalty interest to Biovail.

11. Biovail will provide advisory services to PTL for approximately $400,000 per year.

12. PTL will have limited ability to conduct business other than the development

of the products stipulated in the development agreement. The owners of PTL will be unable to sell their shares, re-organize the company, sell the Company's assets, pay dividends, or incur additional indebtedness (without the agreement of Biovail") while the development agreement is in force

13 At the time of entering into the agreements, Biovail and PTL will not have made any firm arrangements regarding Biovail's role in conducting product development activities on behalf of PTL. However, Biovail will have the right of first refusal to conduct the product development and Biovail and PTL expect to negotiate product development contracts at a later date Biovail is currently not able to perform a substantial portion of the research and development planned by PTL.

14. There will be no fixed time period within which PTL must complete the product development program. Should PTL's product development costs exceed those currently planned and PTL is unable to raise additional capital, the development effort may be resumed and completed by Biovail. In this event, if a product is approved and sold, PTL will receive royalties on a pro rata basis which recognizes the respective development costs assumed by the two parties.

15 Royalties will be payable to PTL based on the sale of any of the six products that are ultimately approved and sold, but only for the treatment of the indication specified by product in the agreement

16. PTL will have the right to develop two additional product opportunities (at its own expense) that have been identified by Biovail if none of the six original products result in commercial applications. PTL will select these two additional opportunities from a list of four opportunities set out in the agreements. Biovail has not performed any significant research and development with respect to these four additional opportunities which, at this time, simply represent initial proposals for possible future development projects As a result, Biovail estimates that the contingent product development opportunity provided to PTL currently has only a nominal fair value

17. PTL intends to acquire $10 million of manufacturing equipment for lease to Biovail. The terms of such lease have not yet been negotiated but it is expected that such lease will be on normal commercial leasing terms between unrelated lessors and lessees.

18. PTL's lender is also a lender to Biovail. All existing and presently contemplated business relationships between the lender and Biovail reflect normal commercial terms between unrelated parties.

Issues

The issue is to determine the appropriate treatment for Biovail under accounting principles generally accepted in the United States for the transaction described above. There are two primary questions to be considered:

1. Should PTL be consolidated within Biovail?
2. Even if consolidation is not appropriate, should Biovail nonetheless account for the project development expenses and liabilities of PTL in its own financial statements?

Question One

Consolidation

Under ARB 51, consolidation is normally required when one party has a majority of the voting interest in another enterprise. Accordingly, under the described situation, Biovail would not normally consolidate PTL as it does not own any voting securities of PTL. There are, however, exceptions to this general rule, which must be considered.

EITF Topic D-14 provides guidance indicating that for non-consolidation to occur:

> "the majority owner (or owners) of the SPE must be an independent third party who has made a substantive capital investment in the SPE, has control of the SPE and has substantive risks and rewards of ownership of the assets of the SPE. Conversely, SEC staff believes that non-consolidation and sales recognition are not appropriate by the sponsor or transferor when the majority owner of the SPE makes only a nominal capital investment, the activities are virtually all on the sponsor's or transferor's behalf and the substantive risks and rewards of the assets or the debt of the SPE rest directly or indirectly with the sponsor or transferor"

In this transaction, the majority owners of PTL have made more than a nominal investment ($1 million) in a company whose only asset is a royalty interest in products that will require an additional $140 million to be spent to complete research and development before reaching commercial production. The debt to be incurred to finance future research and development activities will be provided by third party lenders who have no guarantee from Biovail so the existence of this debt further dilutes the position of the common shareholders if the results of the product development are less than anticipated. Further, the option to assume control of PTL represents a significant decision for Biovail to make. In addition to the $1.75 million need to acquire the common shares, Biovail would also need to assume approximately $140 million of debt in the acquisition. This debt amount is significant to Biovail considering that Biovail could choose to pay

the royalties if it believes that this would be ultimately more economic than repaying any assumed debt. All of these factors support non-consolidation.

Conversely, it can be argued that the activities of PTL are being conducted on behalf of Biovail as Biovail has retained the rights to manufacture and sell any products. However, the PTL owners and lenders know that they are incurring costs in return for a royalty interest in these products. Accordingly the value, risks and rewards of their assets (the royalty interest) and liabilities (the bank lending facilities), while closely aligned with Biovail, do not rest solely with Biovail and do not indicate that consolidation is required.

Since there are arguments that support both consolidation and non-consolidation, there is significant judgment involved in the determination of the appropriate accounting. In our opinion, consolidation is not required given the facts and circumstances described in this letter.

Question Two

Research and Development Arrangements

Further guidance on how to account for this transaction is also contained in FAS 68 which relates to the appropriate accounting for research and development arrangements. In order to determine the appropriate accounting for the funds expended by PTL on product development, one needs to consider whether Biovail is obligated to repay any amounts paid by others for performing the work. There are a number of factors to be evaluated which are specified in paragraphs 6, 7 and 8 of FAS 68 and which are summarized below:

FAS 68 discussion	Application to these facts
6. To conclude that a liability does not exist, the transfer of the financial risk involved with research and development from the enterprise to the other parties must be substantive and genuine. To the extent that the enterprise is committed to repay any of the funds provided by the other parties regardless of the outcome of the research and development, all or part of the risk has not been transferred. The following are some examples in which the enterprise is committed to repay:	You have informed us that there are no contractual guarantees of Biovail or any parties related to Biovail to acquire the common shares of PTL or to repay any funds used to continue the research and development of the products under development by PTL.

a. The enterprise guarantees, or has a contractual commitment that assures, repayment of the funds provided by the other parties regardless of the outcome of the research and development. b. The other parties can require the enterprise to purchase their interest in the research and development regardless of the outcome. c. The other parties automatically will receive debt or equity securities of the enterprise upon termination or completion of the research and development regardless of the outcome.	
7. Even though the written agreements or contracts under the arrangement do not require the enterprise to repay any of the funds provided by the other parties, surrounding conditions might indicate that the enterprise is likely to bear the risk of failure of the research and development. If those conditions suggest that it is probable that the enterprise will repay any of the funds regardless of the outcome of the research and development, there is a presumption that the enterprise has an obligation to repay the other parties. That presumption can be overcome only by substantial evidence to the contrary.	You have informed us that management does not believe that it is probable that it will repay the amounts being advanced and that the funding provided by others should not be recorded as a liability. Some of the factors that should be considered are discussed below.
8. Examples of conditions leading to the presumption that the enterprise will repay the other parties include the following: a. The enterprise has indicated an intent to repay all or a portion of the funds provided regardless of the outcome of the research and development.	It is our understanding that Biovail has not provided any explicit or implicit undertaking to any parties involved in the transaction to repay all or a portion of the funds provided.

b. The enterprise would suffer a severe economic penalty if it failed to repay any of the funds provided to it regardless of the outcome of the research and development. An economic penalty is considered "severe" if in the normal course of business an enterprise would probably choose to pay the other parties rather than incur the penalty. For example, an enterprise might purchase the partnership's interest in the research and development if the enterprise had provided the partnership with proprietary basic technology necessary for the enterprise's ongoing operations without retaining a way to recover that technology, or prevent it from being transferred to another party, except by purchasing the partnership's interest	This is an area of significant management judgment. Although PTL will have a royalty interest in the products to be developed, it does not and will not own any "core technology". Accordingly, a decision to not acquire PTL would not represent a significant economic penalty to Biovail. If the products are successful, Biovail could simply manufacture and market the products and pay the royalty and still obtain a reasonable profit from its efforts. Accordingly, it is our understanding that management does not currently believe that it is probable that it would choose to purchase the common shares of PTL rather than incur any penalty.
c A significant related party relationship between the enterprise and the parties funding the research and development exists at the time the enterprise enters into the arrangement.	There is currently no related party relationship between the parties funding the research and Biovail.
d The enterprise has essentially completed the project before entering into the arrangement.	The technology being developed for PTL is still in various stages of clinical trials and therefore is not complete. Accordingly the initial funds received from the lender would not be the subject of this rule. However, the structure of the lending arrangement, whereby the lender makes annual decisions on additional tranches of funding each year, could put subsequent funding in a different category. If any of the projects are essentially complete and approved by the FDA, then it may be argued that funding provided after this date could be considered differently than the initial funding. We would need to review the facts and circumstances each time a new tranche of financing was received.

Based upon all of the above, it is our opinion that Biovail's recording PTL's project development expenses and liabilities in its own financial statements is not required at this time.

The ultimate responsibility for the appropriate application of generally accepted accounting principles for the transactions described above rests with your management as preparers of the financial statements. Our judgment on the appropriate application of generally accepted accounting principles for the transactions described above is based on the facts, circumstances and assumptions provided to us and as summarized in this letter. Should there be any changes or omissions to the facts, circumstances and assumptions set out in this letter, such changes or omissions could have the effect of changing our opinion.

Furthermore, our conclusion represents our judgment regarding the application of generally accepted accounting principles and the published rules and regulations of the Securities and Exchange Commission in the United States (the "SEC"). Our conclusion is not binding on the SEC or its staff, and there is no assurance that the SEC or its staff will not successfully assert a contrary position.

It is understood that this letter is to be made available solely to the management of Biovail and is not to be referred to or distributed to any other party without our prior written consent.

Yours sincerely,

Ernst & Young LLP

Robert C. Scullion/Douglas L. Cameron
416-943-2549/416-943-3665

Appendix A

1. Introduction

Biovail is sponsoring the formulation of an R&D vehicle that will be owned by third party investors and financed with bank debt. This confidential information memorandum describes the proposed transaction, the structure of the vehicle, the products to be developed by the R&D vehicle and the economics. Biovail is soliciting commitments for debt and equity participation in the vehicle.

Biovail is a fully integrated international pharmaceutical company applying advanced proprietary controlled-release drug delivery technology to the development of superior branded and cost effective generic formulations of medications for the treatment of chronic medical conditions. It is engaged in all stages of pharmaceutical development, from research and development, through clinical testing and regulatory filings to full scale manufacturing.

Biovail markets its products in North America, Europe and more than 50 countries through strategic partnerships and licensing agreements with many of the world's leading pharmaceutical companies. Biovail also markets products directly through its sales and marketing division, Crystaal in Canada and Biovail Pharmaceuticals in the United States, and provides independent clinical and laboratory services to the pharmaceutical industry through its Contract Research Division.

Biovail has executed three significant strategic initiatives during the past eighteen months, investing in excess of $750MM. These initiatives have strengthened Biovail's technological base, expanded its sales and marketing operations into the US market and doubled its size with the number one brand in the cardiovascular therapy market. In late 1999, Biovail acquired Fuisz Technologies with its Flash Dose and Taste Masking technology. In October 2000, DJ Pharma and its 300 person sales force in the US was purchased and in December 2000 the Cardizem family of products was acquired from Aventis.

In 1997 Biovail sponsored the establishment of Intelligent Polymers Limited, an R&D vehicle, that contracted with Biovail to develop several controlled release products. This vehicle, which was purchased in 2000 by Biovail, is the source for Biovail's near term product pipeline. Now Biovail is sponsoring the establishment of the FlashDoseCo R&D vehicle for its mid-term product pipeline.

FlashDoseCo

Pharmaceutical Technologies Limited ("FlashDose Co" or "PTL") will be a newly formed Bermuda exempted company owned by third parties (the "Equity Investors").

FlashDoseCo will raise debt financing that will provide it with the capital to complete the R&D programs for the application of Biovail's Flash Dose ("FD") technology to a basket of four products and to conduct clinical research trials on controlled release ("CR") products. FlashDoseCo will have the right to develop other products currently under Biovail's R&D program should pre-determined milestones not be achieved. Biovail will provide FlashDoseCo with strategic advice under the Advisory Agreement and may provide FlashDoseCo with product development services.

It is contemplated that Biovail will market and manufacture the products on completion of their development. FlashDoseCo will be entitled to royalties from the net sale of the products by Biovail or it licensees. Biovail will have an option to terminate FlashDoseCo's royalty entitlement on payment of amounts to be negotiated prior to closing. Biovail will also have the right to acquire the shares in FlashDoseCo from the Equity Investor.

The products to be developed by FlashDoseCo represent 6 significant products under development in Biovail's mid-term drug pipeline. The drugs to be developed by FlashDoseCo include two products aimed at different segments of the $3.5 billion pain treatment market, two products for the $9 billion anti-depressant market, and one sleep disorder product, and one product in the $1.7 billion general anxiety disorder market.

The table below summarizes the products to be developed by FlashDoseCo, the technology to be applied – FD, CR, or both FD and CR, the budgeted expenditures, the targeted launch date and the projected stabilized sales level.

Product Overview

(USD Millions)

Current Status	Branded Product	Technology	Indication	R&D Budget	Targeted Approval Date	Target Launch	Current Branded Revenue	Target Biovail Revenue
Phase III	Buspirone	CR	Anti-Anxiety	$7	Q3/03	Q3/03	$700	$500
Scale Up	Fluoxetine	FD	Depression	$4	Q1/03	Q1/05	$2,350	$350
Phase I	Oxycodone	FD/CR	Pain	$20	Q2/05	Q4/06	$1,200	$760
Phase I	Paroxetine	FD	Depression and Anxiety	$5	Q2/03	Q3/04	$1,650	$240
Phase III	Tramadol	CR	Pain	$35	Q3/05	Q1/05	$1,500	$210
Phase I	Zolpidem	FD/CR	Sleep disorders	$11	Q4/03 Q2/04	Q4/06 Q4/06	$ 700	$130
Allocated				$82			$7,100	$1,190
Unallocated				$11				
Total R&D				$93				
General, Interest and Other (net)				$37				
Total Costs				$130				

Source: IMS LTM Dec/2000

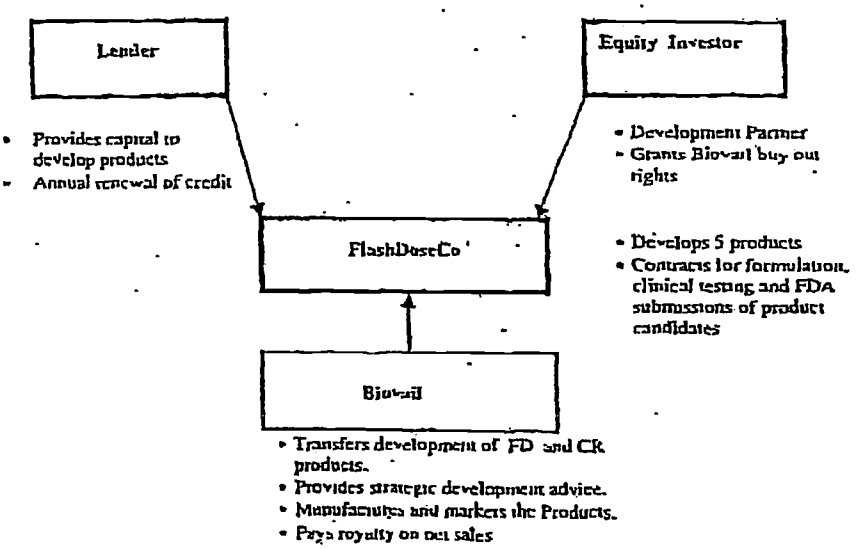
Biovail intends to launch these products when any applicable patents to the innovator drugs have expired. Biovail may alternatively out-license its Flash Dose technology application to the branded product to its innovator. This second approach would allow Biovail earlier direct access to the market as it would preclude any patent expiry issues, and would allow the innovator to extend its brand exclusivity.

In addition, FlashDoseCo will acquire and install $10 million of equipment to scale-up Flash Dose production in Biovail's Puerto Rico production facility, resulting in a total funding requirement for FlashDoseCo over three years of $140MM.

FlashDoseCo will fund all development expenses on the products from January 1, 2001 and the transaction is to close prior to June 30, 2001.

2. Transaction Summary

- Equity Investor to invest $1MM in capital of FlashDoseCo
- FlashDoseCo will raise $130MM in capital for its R&D program in three annual tranches of $60MM, $40MM and $30MM.
- FlashDoseCo will complete the research and development programs for a portfolio of Flash Dose products and controlled release products under an exclusive technology license arrangement with Biovail to apply its Controlled-Release and Flash Dose technologies to certain products. Biovail will retain ownership of the underlying Controlled Release and Flash Dose technologies
- Biovail will provide FlashDoseCo with strategic development advice on its R&D program
- FlashDoseCo will contract with third parties, and potentially with Biovail affiliates, to conduct the research and development program. Biovail will have first right of refusal on the development of these products.
- FlashDoseCo will acquire and install $10MM of production equipment in Biovail's Dorado, Puerto Rico facility and lease that equipment to Biovail. Biovail will hold an option to purchase the equipment from FlashDoseCo
- Biovail and/or its licensees will manufacture and market the approved drugs
- FlashDoseCo will earn royalties from the net sale of the products by Biovail and/or its licensees
- Biovail will hold a purchase option to buy out FlashDoseCo's entitlement to the Royalties in return for payment of specified amounts, and an option to purchase its shares from the Equity Investor.



3. Summary of Terms and Conditions

June 8, 2001

PROJECT FLASHDOSE

SUMMARY OF TERMS AND CONDITIONS

The following is intended as a summary outline of the principal terms and conditions which will govern the proposed structure and financing of FlashDoseCo and which will be set forth in one or more definitive transaction agreements.

FLASHDOSECO	FlashDoseCo, a newly incorporated corporation to be formed under the laws of ■. The directors of FlashDoseCo will be appointed by the Equity Investor (as defined below). The voting shares of FlashDoseCo will be owned by the Equity Investor. FlashDoseCo will contract with BLI to complete the research and development program ("R&D Program") for the application of the FlashDose technology (the "Fb Technology") to four products and the completion of the application of BLI's Controlled Release technology (the "CR Technology") to one other product (namely Tramadol). FlashDoseCo will contract with ● to provide FlashDoseCo with executive, financial, management and administrative services.
BIOVAIL	Biovail Corporation
BLI	Biovail Laboratories Inc.
EQUITY INVESTOR	●
LENDER	●
EQUITY COMMITMENT	For an aggregate investment of $■, FlashDoseCo will issue ■ shares to the Equity Investor as FlashDoseCo's initial capitalization
DEBT COMMITMENT	In addition, FlashDoseCo will enter into a credit facility with (or issue debt instruments to) the Lender in the amount of approximately $140 million for purposes of the funding of the R&D Expenditures and the purchase and installation of the Equipment (as defined below)

TERM OF DEBT / ANNUAL REVIEW	Biovail and BLI will make appropriate personnel and information available to FlashDoseCo to assist it in its initial negotiations with the Lender. It is anticipated that the terms of FlashDoseCo's debt will provide for an annual review by the Lender of the progress of the R&D Program. Biovail and BLI will also make appropriate personnel and information available to FlashDoseCo to assist it with the annual credit review discussions with the Lender.
ROYALTY DEVELOPMENT AGREEMENT	In the Royalty Development Agreement, BLI will grant FlashDoseCo a non-assignable (other than to its lender as security) license to its FD Technology and CR Technology (collectively the "Technology"), exclusively for the R&D Program. FlashDoseCo will be entitled to earn a royalty from BLI from the sale of the products to which the Technology has been applied (the "Products") by BLI or its licensees for a period of 10 years from the launch of each Product. The Royalty will be at the rate of 5, 7 and 10% of Net Sales of the Products (for years 1 and 2, years 3 and 4, and years 5 through 10, respectively) and 20% of royalties earned by BLI on an out-licensing of a Product, from the launch of each Product. BLI or its licensees shall manufacture and market the Products To the extent possible, BLI will assign, or cause to be assigned, to FlashDoseCo all existing clinical and developmental contracts in respect of the current development of the Products and the Technology as it applies to the Products. The transaction will include a product liability indemnity in favour of FlashDoseCo, that is consistent with industry practices. As part of the R & D Program, FlashDoseCo will agree to complete or cause completion of the research and development work (including PK studies and Phase III and IV studies) and will incur the costs (the "R&D Expenditures") to be expended for the application of the Technology to the Products for a three year period. FlashDoseCo may, at its option, on 30 days' written notice to BLI, exercise its right to cease to incur any further R&D Expenditures, if either of the following events occurs: a) FlashDoseCo determines that the net present value of the expected future royalty stream under the Royalty Development Agreement is less than the estimated cost required to be incurred to commercialize the Products, or

b) FlashDoseCo determines that BLI will not have the financial capacity to commercialize the Products upon the completion of FlashDoseCo's development of the Products

The initial budget for the R & D Expenditures for each Product (the "R & D Budget") will be attached as a schedule to the Royalty Development Agreement. A revised R & D Budget will be reviewed and agreed to by FlashDoseCo and BLI at least once every six months

TRAMADOL CR OPTION

In the Royalty Development Agreement, BLI will be granted an option (the "Tramadol CR Option") exercisable on 30 days' notice to terminate FlashDoseCo's development of Tramadol CR under the Royalty Development Agreement at any time and from time to time.

The exercise price for the Tramadol CR Option from time to time shall be an amount equal to the greater of (i) excess of the net present value of FlashDoseCo's expected royalty stream from the sale of Tramadol CR under the Royalty Development Agreement, over the net present value of the R & D Expenditures forecast in the most recent R & D Budget for Tramadol CR (as provided for above under "Royalty Development Agreement"), and (ii) $25 million. For the purposes of determining the amount in (i) above, the net present value of the expected future royalties at each quarter-end, and the net present value of the forecast R & D Expenditures as of the date hereof are as set out on Appendix A hereto. The amounts shown on Appendix A for the expected future royalties will be revised from time-to time using the same discount rate and methodology and the R & D Expenditures will be updated to reflect the most recent R & D Budget as described above

SUBSTITUTION RIGHTS

FlashDoseCo will be entitled to perform the R&D Program related to the application of FD Technology to up to two additional products (which shall be included as "Products" under the Royalty Development Agreement) in the event that all of the initial Products are reasonably determined to be no longer commercially feasible, as described in (a) under "Royalty Development Agreement" above or if the product development and commercialization milestones described in (a) and (b) under "Events of Termination" (see below) are not achieved

FLASHDOSECO COVENANT	During the term of the relevant agreements, FlashDoseCo will not sell, transfer, license or otherwise dispose of its interest (or any part thereof) in the Royalty Development Agreement without BLI's consent to any party other than to BLI or an affiliate of BLI FlashDoseCo will be subject to certain restrictive covenants with respect to its assets and corporate actions. The restrictions will include the payment of dividends, corporate restructurings, sale or disposition of material assets, creation of liens on material assets, and the carrying on of other business activities.
ADVISORY AGREEMENT	FlashDoseCo and BLI will also enter into an Advisory Agreement pursuant to which: (a) BLI will provide advisory services (the "Services") to FlashDoseCo for the development of the Products; (b) the Services will include strategic advice on formulation, clinical development, regulatory strategy and commercial exploitation; and (c) BLI will be paid for the provision of the Services at the rate of $100,000 per quarter, plus out-of-pocket expenses
PRODUCT DEVELOPMENT AGREEMENTS	FlashDoseCo will enter into one or more Product Development Agreement(s) for the conducting of and/or arrangement for the research and development services for the Products (including formulation and clinical research services) (the "Product Development Services"). Each Product Development Agreement will contain typical change of control, performance and credit default provisions Biovail will be granted the first right of offer to provide the Product Development Services under each Product Development Agreement.
PRODUCTION EQUIPMENT	FlashDoseCo will acquire and arrange for the installation of the equipment train (the "Equipment") for the production of the FlashDose Products in BLI's plant in Dorado, Puerto Rico. The estimated cost of the Equipment and related transitional costs is approximately $10 million. FlashDoseCo will lease the installed Equipment to BLI at the rate of $* per year.

The equipment train will include a blender, microsphere towers, bead tower, bead coater and a packaging line.

BLI will be granted an option (the "Equipment Purchase Option") to purchase the Equipment from FlashDoseCo at any time and from time to time. The exercise price of the Equipment Purchase Option will be:

During Year 1 - $ ■
After Year 1 - $ ■
After Year 2 - $ ■
After Year 3 - $ ■
After Year 4 - $ ■

FlashDoseCo will not sell, transfer, pledge or otherwise dispose of the Equipment during the term of the Equipment Purchase Option

BLI ROYALTY PURCHASE OPTION

In the Royalty Development Agreement, BLI will be granted an option (the "Royalty Purchase Option") exercisable on 30 days' written notice to terminate FlashDoseCo's entitlement to royalties under the Royalty Development Agreement, at any time and from time to time. The exercise price of the Royalty Purchase Option will be as follows

Prior to 12/31/02 - $110 million
Prior to 6/30/03 - $120 million
Prior to 12/31/03 - $135 million
Prior to 6/30/04 - $140 million
Prior to 12/31/04 - $150 million
Prior to 12/31/05 - $175 million
Prior to 12/31/06 - $195 million

The amounts above will be reduced by the amount paid by BLI on exercise of the Tramadol CR Option

The closing of the exercise of the Royalty Purchase Option will be within 15 days of exercise.

SHARES PURCHASE OPTION

BLI will also be granted an option (the "Shares Purchase Option") exercisable on 30 days' written notice to purchase all of the Equity Investor's shares in FlashDoseCo at any time and from time to time. The exercise price of the Shares Purchase Option will be:

Prior to 12/31/02 – $1.75 million
Prior to 6/30/03 - $2 million
Prior to 12/31/03 – $2.25 million
Prior to 6/30/04 - $2.5 million
Prior to 12/31/04 - $3 million
Prior to 12/31/05 - $4 million
Prior to 12/31/06 – $5 million

The Equity Investor shall not sell, transfer, pledge or otherwise dispose, directly or indirectly, of its shares in FlashDoseCo during the term of the Shares Purchase Option.

EVENTS OF TERMINATION

Each of the following events shall be a "Termination Event" for purposes hereof

a) An NDA or ANDA, as applicable, has not been filed for at least one of the Products within two years from the execution of the Advisory Agreement.

b) If Biovail or BLI has not, within three years from the execution of the Royalty Development Agreement, commercialized at least one Product within one year of that product receiving approval of its NDA or ANDA, as applicable;

c) If the Lender does not advance further funds to FlashDoseCo after any annual review of the progress of its R&D Program and Biovail is not willing to provide FlashDoseCo with, or arrange financing, on commercially reasonable terms and rates.

d) A default by Biovail under the terms of any material financing agreement, or

e) A change in control of Biovail

CONSEQUENCES OF TERMINATION EVENTS

Following the occurrence of a Termination Event, FlashDoseCo may, at its option, terminate the Shares Purchase Option on 30 days' written notice. Immediately after termination of the Shares Purchase Option, FlashDoseCo may, at its option, terminate:

i) the Royalty Development Agreement,

ii) the Advisory Agreement; and

iii) any Product Development Agreement(s) to which BLI (or an affiliate thereof) is a party

The Lender will not enforce any of its recourse rights under the credit facility (or debt instruments) with FlashDoseCo until after the cancellation of the Royalty Repurchase Option and the Shares Purchase Option.

TRAILING ROYALTIES

If FlashDoseCo terminates the agreements, as provided for above under "Consequences of Termination Events", BLI will grant FlashDoseCo a fully vested carried interest in revenues from the Products entitling it to royalties from the future sale of the Products ("Trailing Royalties") at the rate under the Royalty Development Agreement multiplied by the degree of completion (determined by the ratio of expenditures incurred to date relative to the most recent R&D Budget) of the R&D Program for each Product at the time of termination

BLI shall have the option to terminate the obligation to pay Trailing Royalties on the payment of $● to FlashDoseCo

If FlashDoseCo elects to cease funding R&D Expenditures after either of the events described in paragraph a) or b) under the "Royalty Development Agreement" above, then it shall be entitled to a trailing royalty equal to 50% of the Trailing Royalties described above and such obligations may be terminated by BLI on the payment of $● to FlashDoseCo

COOPERATION

Biovail, BLI, FlashDoseCo and the Equity Investor will cooperate with each other to structure, implement and complete the transactions contemplated herein in an efficient manner (with a view to maximizing transaction costs and structuring the transactions in a tax effective manner)

DOCUMENTATION

This term sheet represents an outline of the basis on which FlashDoseCo, the Equity Investor and the Lender, respectively, will be prepared to provide the Equity Commitment and Debt Commitment (the "Commitments") and enter into the agreements and other arrangements contemplated herein. It is not exhaustive as to the terms and conditions which will govern the Commitments and such agreements and other arrangements contemplated herein and negotiation will be required to finalize the terms and conditions of the transactions and structure

The arrangements between FlashDoseCo, Biovail, and BLI will be addressed in further detail in a non-binding letter of intent.

The transactions will be effected on the completion of documentation (referred to herein as the "Definitive Documents") including definitive versions of the agreements referred to herein which will contain the terms and conditions set out herein, in addition to customary conditions precedent, representations and warranties.

covenants, events of default, rights of set-off, and indemnity provisions and other terms, conditions and provisions customary for transactions of this kind. The Definitive Documents will governed by the laws of Ontario

CONDITIONS PRECEDENT

Without limiting the other terms of this term sheet, any obligation to complete the transactions contemplated herein will be subject to the fulfillment of the following conditions on or prior to the closing date:

a) Negotiation of financing by FleshDoseCo on commercially reasonable terms;

b) Completion and execution of the Definitive Documents;

c) Approval by the boards of directors of Biovail and BLI; and

d) Satisfactory completion of due diligence by the Equity Investor and its lender

TIMING

The parties expect to execute a detailed non-binding letter of intent by ■ and execute the Definitive Documents by ■

BIOVAIL
Corporation

June 19, 2003

Mr. Stan Hull
Glaxo SmithKline
Sr. Vice-President – US
Five Moore Drive
F2200
Research Triangle Park, NC
27709

Dear Mr. Hull

We are writing with respect to our recent discussions concerning the supply of Wellbutrin XL ("WBXL") by Biovail to GSK. Despite Biovail's repeated requests, GSK has not finalized on an order of trade supplies of WBXL from Biovail in Q2, 2003, but has asked Biovail to ship quantities of WBXL for packaging as samples only. GSK took this position only after Biovail had agreed to reduce the price for samples significantly and which therefore produces no net profit for Biovail. This reduction was a major concession made by Biovail to GSK in the spirit of what we expected to be continuing cooperation between our respective companies.

You will recall that, in June of 2002, representatives of Biovail had a meeting with David Stout and yourself of GSK, at which time we discussed Biovail's requirement to ship trade supplies of WBXL to you in Q2 of 2003. We discussed the minimum pricing needed by Biovail for those initial shipments. It was our understanding that we had verbally agreed both on the timing of those shipments and the pricing of the product, so that Biovail could be assured that it could book the revenue associated with those shipments in Q2 of 2003.

We have reiterated our understanding of this agreement, and our need for the forecasts and purchase orders that would implement this agreement, on several occasions at successive meetings and conference calls with you. We discussed this during our last meeting in Philadelphia. At that meeting, Mr. J.P. Garnier expressed the view that Biovail's request was reasonable and he agreed that there should be no downward reconciliation of the invoice price, notwithstanding the wording of the WBXL Agreement.

This is an issue that we have been discussing for over one year. Biovail's understanding of this agreement has been part of Biovail's planning since last June. Because we have not been able to obtain from you either a forecast or a purchase order that would implement the agreement that we thought we had reached, despite the two months that have passed since our last meeting, we have not committed the resources that we would

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Mississauga, Ontario Canada
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T 905 286 3000
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www.biovail.com

have to commit, (which are otherwise dedicated to the production of Biovail's other products) to produce the quantities of products that would be required to ship both samples and trade supplies in the volumes we had discussed.

Although we have experienced some initial production difficulties, that are the subject of another letter to you, we remain willing, as we have discussed, to produce and sell to you in Q2 all of our current production of WBXL as bulk trade product, which you are entitled to order under the agreement. The pricing, as we have discussed, should be $12.31 per bottle of 30, 150 mg tablets (252,000 bottles) and $14.21 per bottle of 30, 300 mg tablets (651,000 bottles), plus $1.00 for subsequent packaging once the label and package insert is final. (As we have previously agreed, there would be no downward reconciliation of the purchase price that would apply to this initial shipment.)

We expect to be able to fulfill your requirements for samples early in July.

We look forward to our telephone conversation today at 4:00pm EST to discuss this proposal with you, and to receiving confirmation of your acceptance of these terms.

Yours very truly,

Brian Crombie
Sr. V.P. & CFO

CC: Eugene Melnyk
Ken Cancellara
Carol Chapuis

Biovail Corporation
7150 Mississauga Road
Mississauga, Ontario Canada
L5N 8M5
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-515

GlaxoSmithKline
Attention: Mary E. Martinson
Director, Regulatory Affairs, Psychiatry
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

Dear Ms. Martinson:

Please refer to your new drug application (NDA) dated August 26, 2002, received August 26, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Wellbutrin XL (bupropion hydrochloride extended-release) Tablets.

We acknowledge receipt of your submissions dated July 3, 2003, August 21, 2003, and August 28, 2003. The July 3, 2003 submission constituted a complete response to our June 24, 2003 action letter.

This new drug application provides for the use of Wellbutrin XL (bupropion hydrochloride extended-release) tablets as a new extended-release formulation of bupropion.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Labeling

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, and immediate container and carton labels). Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission **"FPL for approved NDA 21-515."** Approval of this submission by FDA is not required before the labeling is used.

Drug Product Expiry

The expiration date presently approved for Wellbutrin XL 150 mg and 300 mg Tablets in the 7 and 30 count bottle is 12 months.

Dissolution Specifications

Following is the approved *in vitro* dissolution specifications for both strengths of Wellbutrin XL 150 mg and 300 mg tablets:

Apparatus:	USP Apparatus 1 (Basket) at 75 RPM	
Medium:	900mL of 0.1N hydrochloric acid at 37± 0.5°C	
Specifications:	2 hours:	Not more than 20%
	4 hours:	20-45%
	8 hours:	65-85%
	16 hours:	Not less than 80%
Sample size:	12 tablets for each time point in the dissolution profile	

Risk Management Plan and Post-Marketing Commitment

We have reviewed your proposed risk management plan included in the July 3, 2003 submission and overall, find your proposal to be acceptable. However, as discussed with you, we consider the Healthcare Practitioner letters and Educational Communication Plan to be essential components of this risk management plan and remind you of your postmarketing commitment dated August 28, 2003. This commitment is listed below.

> Educational Communication Plan: We note your agreement to provide all components of your Educational Communication Plan for Wellbutrin XL (bupropion hydrochloride extended-release tablets) on or before December 15, 2003.
>
> Please submit these educational materials as a package to the NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of this commitment in your annual report to this NDA. The status summary should include expected completion dates and any changes in plans since the last annual report. All submissions, including supplements, relating to this postmarketing commitment must be prominently labeled **"Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."**

Finally, we recommend the following labeling revisions for your companion NDA for Wellbutrin SR Tablets (NDA# 20-358) to minimize potential errors with the use of Wellbutrin XL Tablets since there is a potential for confusion between the two products:

- Include "twice-a-day" text on container labels and carton labeling of the marketed product Wellbutrin SR Tablets (NDA 20-358). (Due to the 150 mg daily initial dosing for Wellbutrin SR Tablets, we recommend that this labeling statement be accompanied by a reference to full dosing information [e.g., "See package insert for full dosage information."])

Patient Education

We also have the following recommendations regarding patient education and related materials:

- All patient information materials (e.g., tear-off sheets, brochures, website, etc.) should contain language that is consistent with the patient package insert (PPI).
- Healthcare providers should be encouraged to provide appropriate education regarding Wellbutrin XL Tablets to their patients, and to reinforce this information by providing the patient with a PPI. Our rationale for this recommendation is below.

  With a few exceptions, PPIs are not required by law to be distributed at time of dispensing. PPIs are discretionary and usually do not accompany prescription medicines at the time of

dispensing for various reasons. Wellbutrin XL will be supplied in bottles of 30 as 150 mg or 300 mg tablets. Even if the PPI is packaged with these bottles, the following factors may diminish the percentage of patients receiving a PPI. The dose of Wellbutrin XL ranges from 150 mg to 450 mg per day. Pharmacies may repackage medications from these packaged amounts when the prescribed amount differs from the packaged amount, or when they have a low supply of the medication on hand and can only dispense a partial prescription.

Methods Validation

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

Promotional Materials

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division/ the Division of Neuropharmacological Drug products and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

MedWatch-to-Manufacturer Program

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Doris J. Bates, Ph.D., Regulatory Project Manager, at (301) 594-2850.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

PRESCRIBING INFORMATION

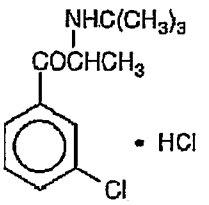
WELLBUTRIN XL™

(bupropion hydrochloride extended-release tablets)

"Patient Information" enclosed.

DESCRIPTION

WELLBUTRIN XL (bupropion hydrochloride), an antidepressant of the aminoketone class, is chemically unrelated to tricyclic, tetracyclic, selective serotonin re-uptake inhibitor, or other known antidepressant agents. Its structure closely resembles that of diethylpropion; it is related to phenylethylamines. It is designated as (±)-1-(3-chlorophenyl)-2-[(1,1-dimethylethyl)amino]-1-propanone hydrochloride. The molecular weight is 276.2. The molecular formula is $C_{13}H_{18}ClNO \cdot HCl$. Bupropion hydrochloride powder is white, crystalline, and highly soluble in water. It has a bitter taste and produces the sensation of local anesthesia on the oral mucosa. The structural formula is:



WELLBUTRIN XL Tablets are supplied for oral administration as 150-mg and 300-mg, creamy-white to pale yellow extended-release tablets. Each tablet contains the labeled amount of bupropion hydrochloride and the inactive ingredients: ethylcellulose aqueous dispersion (NF), glyceryl behenate, methacrylic acid copolymer dispersion (NF), polyvinyl alcohol, polyethylene glycol, povidone, silicon dioxide, and triethyl citrate. The tablets are printed with edible black ink.

The insoluble shell of the extended-release tablet may remain intact during gastrointestinal transit and is eliminated in the feces.

CLINICAL PHARMACOLOGY

Pharmacodynamics: Bupropion is a relatively weak inhibitor of the neuronal uptake of norepinephrine, serotonin, and dopamine, and does not inhibit monoamine oxidase. While the mechanism of action of bupropion, as with other antidepressants, is unknown, it is presumed that this action is mediated by noradrenergic and/or dopaminergic mechanisms.

Pharmacokinetics: Bupropion is a racemic mixture. The pharmacologic activity and pharmacokinetics of the individual enantiomers have not been studied. The mean elimination half-life (±SD) of bupropion after chronic dosing is 21 (±9) hours, and steady-state plasma concentrations of bupropion are reached within 8 days.

In a study comparing 14-day dosing with WELLBUTRIN XL Tablets 300 mg once daily to the immediate-release formulation of bupropion at 100 mg 3 times daily, equivalence was demonstrated for peak plasma concentration and area under the curve for bupropion and the 3 metabolites (hydroxybupropion, threohydrobupropion, and erythrohydrobupropion).

Absorption: Following oral administration of WELLBUTRIN XL Tablets to healthy volunteers, time to peak plasma concentrations for bupropion was approximately 5 hours and food did not affect the C_{max} or AUC of bupropion.

Distribution: In vitro tests show that bupropion is 84% bound to human plasma proteins at concentrations up to 200 mcg/mL. The extent of protein binding of the hydroxybupropion metabolite is similar to that for bupropion, whereas the extent of protein binding of the threohydrobupropion metabolite is about half that seen with bupropion.

Metabolism: Bupropion is extensively metabolized in humans. Three metabolites have been shown to be active: hydroxybupropion, which is formed via hydroxylation of the *tert*-butyl group of bupropion, and the amino-alcohol isomers threohydrobupropion and erythrohydrobupropion, which are formed via reduction of the carbonyl group. In vitro findings suggest that cytochrome P450IIB6 (CYP2B6) is the principal isoenzyme involved in the formation of hydroxybupropion, while cytochrome P450 isoenzymes are not involved in the formation of threohydrobupropion. Oxidation of the bupropion side chain results in the formation of a glycine conjugate of meta-chlorobenzoic acid, which is then excreted as the major urinary metabolite. The potency and toxicity of the metabolites relative to bupropion have not been fully characterized. However, it has been demonstrated in an antidepressant screening test in mice that hydroxybupropion is one half as potent as bupropion, while threohydrobupropion and erythrohydrobupropion are 5-fold less potent than bupropion. This may be of clinical importance because the plasma concentrations of the metabolites are as high or higher than those of bupropion.

Because bupropion is extensively metabolized, there is the potential for drug-drug interactions, particularly with those agents that are metabolized by the cytochrome P450IIB6 (CYP2B6) isoenzyme. Although bupropion is not metabolized by cytochrome P450IID6 (CYP2D6), there is the potential for drug-drug interactions when bupropion is co-administered with drugs metabolized by this isoenzyme (see PRECAUTIONS: Drug Interactions).

In humans, peak plasma concentrations of hydroxybupropion occur approximately 7 hours after administration of WELLBUTRIN XL. Following administration of WELLBUTRIN XL, peak plasma concentrations of hydroxybupropion are approximately 7 times the peak level of the parent drug at steady state. The elimination half-life of hydroxybupropion is approximately 20 (±5) hours, and its AUC at steady state is about 13 times that of bupropion. The times to peak concentrations for the erythrohydrobupropion and threohydrobupropion metabolites are similar to that of the hydroxybupropion metabolite. However, their elimination half-lives are longer, approximately 33 (±10) and 37 (±13) hours, respectively, and steady-state AUCs are 1.4 and 7 times that of bupropion, respectively.

Bupropion and its metabolites exhibit linear kinetics following chronic administration of 300 to 450 mg/day.

Elimination: Following oral administration of 200 mg of ^{14}C-bupropion in humans, 87% and 10% of the radioactive dose were recovered in the urine and feces, respectively. However, the fraction of the oral dose of bupropion excreted unchanged was only 0.5%, a finding consistent with the extensive metabolism of bupropion.

Population Subgroups: Factors or conditions altering metabolic capacity (e.g., liver disease, congestive heart failure [CHF], age, concomitant medications, etc.) or elimination may be expected to influence the degree and extent of accumulation of the active metabolites of bupropion. The elimination of the major metabolites of bupropion may be affected by reduced renal or hepatic function because they are moderately polar compounds and are likely to undergo further metabolism or conjugation in the liver prior to urinary excretion.

Hepatic: The effect of hepatic impairment on the pharmacokinetics of bupropion was characterized in 2 single-dose studies, one in patients with alcoholic liver disease and one in patients with mild to severe cirrhosis. The first study showed that the half-life of hydroxybupropion was significantly longer in 8 patients with alcoholic liver disease than in 8 healthy volunteers (32±14 hours versus 21±5 hours, respectively). Although not statistically significant, the AUCs for bupropion and hydroxybupropion were more variable and tended to be greater (by 53% to 57%) in patients with alcoholic liver disease. The differences in half-life for bupropion and the other metabolites in the 2 patient groups were minimal.

The second study showed no statistically significant differences in the pharmacokinetics of bupropion and its active metabolites in 9 patients with mild to moderate hepatic cirrhosis compared to 8 healthy volunteers. However, more variability was observed in some of the pharmacokinetic parameters for bupropion (AUC, C_{max}, and T_{max}) and its active metabolites ($t_{½}$) in patients with mild to moderate hepatic cirrhosis. In addition, in patients with severe hepatic cirrhosis, the bupropion C_{max} and AUC were substantially increased (mean difference: by approximately 70% and 3-fold, respectively) and more variable when compared to values in healthy volunteers; the mean bupropion half-life was also longer (29 hours in patients with severe hepatic cirrhosis vs 19 hours in healthy subjects). For the metabolite hydroxybupropion, the mean C_{max} was approximately 69% lower. For the combined amino-alcohol isomers threohydrobupropion and erythrohydrobupropion, the mean C_{max} was approximately 31% lower. The mean AUC increased by about 1½-fold for hydroxybupropion and about 2½-fold for threo/erythrohydrobupropion. The median T_{max} was observed 19 hours later for hydroxybupropion and 31 hours later for threo/erythrohydrobupropion. The mean half-lives for hydroxybupropion and threo/erythrohydrobupropion were increased 5- and 2-fold, respectively, in patients with severe hepatic cirrhosis compared to healthy volunteers (see WARNINGS, PRECAUTIONS, and DOSAGE AND ADMINISTRATION).

Renal: The effect of renal disease on the pharmacokinetics of bupropion has not been studied. The elimination of the major metabolites of bupropion may be affected by reduced renal function.

Left Ventricular Dysfunction: During a chronic dosing study with bupropion in 14 depressed patients with left ventricular dysfunction (history of CHF or an enlarged heart on

x-ray), no apparent effect on the pharmacokinetics of bupropion or its metabolites was revealed, compared to healthy volunteers.

Age: The effects of age on the pharmacokinetics of bupropion and its metabolites have not been fully characterized, but an exploration of steady-state bupropion concentrations from several depression efficacy studies involving patients dosed in a range of 300 to 750 mg/day, on a 3 times daily schedule, revealed no relationship between age (18 to 83 years) and plasma concentration of bupropion. A single-dose pharmacokinetic study demonstrated that the disposition of bupropion and its metabolites in elderly subjects was similar to that of younger subjects. These data suggest there is no prominent effect of age on bupropion concentration; however, another pharmacokinetic study, single and multiple dose, has suggested that the elderly are at increased risk for accumulation of bupropion and its metabolites (see PRECAUTIONS: Geriatric Use).

Gender: A single-dose study involving 12 healthy male and 12 healthy female volunteers revealed no sex-related differences in the pharmacokinetic parameters of bupropion.

Smokers: The effects of cigarette smoking on the pharmacokinetics of bupropion were studied in 34 healthy male and female volunteers; 17 were chronic cigarette smokers and 17 were nonsmokers. Following oral administration of a single 150-mg dose of bupropion, there was no statistically significant difference in C_{max}, half-life, T_{max}, AUC, or clearance of bupropion or its active metabolites between smokers and nonsmokers.

CLINICAL TRIALS

The efficacy of bupropion as a treatment for major depressive disorder was established with the immediate-release formulation of bupropion in two 4-week, placebo-controlled trials in adult inpatients and in one 6-week, placebo-controlled trial in adult outpatients. In the first study, patients were titrated in a bupropion dose range of 300 to 600 mg/day of the immediate-release formulation on a 3 times daily schedule; 78% of patients received maximum doses of 450 mg/day or less. This trial demonstrated the effectiveness of bupropion on the Hamilton Depression Rating Scale (HDRS) total score, the depressed mood item (item 1) from that scale, and the Clinical Global Impressions (CGI) severity score. A second study included 2 fixed doses of the immediate-release formulation of bupropion (300 and 450 mg/day) and placebo. This trial demonstrated the effectiveness of bupropion, but only at the 450-mg/day dose of the immediate-release formulation; the results were positive for the HDRS total score and the CGI severity score, but not for HDRS item 1. In the third study, outpatients received 300 mg/day of the immediate-release formulation of bupropion. This study demonstrated the effectiveness of bupropion on the HDRS total score, HDRS item 1, the Montgomery-Asberg Depression Rating Scale, the CGI severity score, and the CGI improvement score.

Although there are no independent trials demonstrating the antidepressant effectiveness of WELLBUTRIN XL, studies have demonstrated similar bioavailability of the immediate-release and the extended-release formulations of bupropion under steady-state conditions, i.e., WELLBUTRIN XL 300 mg once daily was shown to have bioavailability that was similar to that

of 100 mg 3 times daily of the immediate-release formulation of bupropion, with regard to both rate and extent of absorption, for parent drug and metabolites.

In a longer-term study, outpatients meeting DSM-IV criteria for major depressive disorder, recurrent type, who had responded during an 8-week open trial on bupropion (150 mg twice daily of the sustained-release formulation) were randomized to continuation of their same dose of bupropion or placebo, for up to 44 weeks of observation for relapse. Response during the open phase was defined as CGI Improvement score of 1 (very much improved) or 2 (much improved) for each of the final 3 weeks. Relapse during the double-blind phase was defined as the investigator's judgment that drug treatment was needed for worsening depressive symptoms. Patients receiving continued bupropion treatment experienced significantly lower relapse rates over the subsequent 44 weeks compared to those receiving placebo.

INDICATIONS AND USAGE

WELLBUTRIN XL is indicated for the treatment of major depressive disorder.

The efficacy of bupropion in the treatment of a major depressive episode was established in two 4-week controlled trials of inpatients and in one 6-week controlled trial of outpatients whose diagnoses corresponded most closely to the Major Depression category of the APA Diagnostic and Statistical Manual (DSM) (see CLINICAL PHARMACOLOGY).

A major depressive episode (DSM-IV) implies the presence of 1) depressed mood or 2) loss of interest or pleasure; in addition, at least 5 of the following symptoms have been present during the same 2-week period and represent a change from previous functioning: depressed mood, markedly diminished interest or pleasure in usual activities, significant change in weight and/or appetite, insomnia or hypersomnia, psychomotor agitation or retardation, increased fatigue, feelings of guilt or worthlessness, slowed thinking or impaired concentration, a suicide attempt, or suicidal ideation.

The efficacy of bupropion in maintaining an antidepressant response for up to 44 weeks following 8 weeks of acute treatment was demonstrated in a placebo-controlled trial with the sustained-release formulation of bupropion (see CLINICAL PHARMACOLOGY). Nevertheless, the physician who elects to use WELLBUTRIN XL for extended periods should periodically reevaluate the long-term usefulness of the drug for the individual patient.

CONTRAINDICATIONS

WELLBUTRIN XL is contraindicated in patients with a seizure disorder.

WELLBUTRIN XL is contraindicated in patients treated with ZYBAN® (bupropion hydrochloride) Sustained-Release Tablets, WELLBUTRIN (bupropion hydrochloride) the immediate-release formulation, WELLBUTRIN SR (bupropion hydrochloride) the sustained-release formulation, or any other medications that contain bupropion because the incidence of seizure is dose dependent.

WELLBUTRIN XL is contraindicated in patients with a current or prior diagnosis of bulimia or anorexia nervosa because of a higher incidence of seizures noted in patients treated for bulimia with the immediate-release formulation of bupropion.

WELLBUTRIN XL is contraindicated in patients undergoing abrupt discontinuation of alcohol or sedatives (including benzodiazepines).

The concurrent administration of WELLBUTRIN XL Tablets and a monoamine oxidase (MAO) inhibitor is contraindicated. At least 14 days should elapse between discontinuation of an MAO inhibitor and initiation of treatment with WELLBUTRIN XL Tablets.

WELLBUTRIN XL is contraindicated in patients who have shown an allergic response to bupropion or the other ingredients that make up WELLBUTRIN XL Tablets.

WARNINGS

Patients should be made aware that WELLBUTRIN XL contains the same active ingredient found in ZYBAN, used as an aid to smoking cessation treatment, and that WELLBUTRIN XL should not be used in combination with ZYBAN, or any other medications that contain bupropion, such as WELLBUTRIN SR (bupropion hydrochloride), the sustained-release formulation or WELLBUTRIN (bupropion hydrochloride), the immediate-release formulation.

Seizures: Bupropion is associated with a dose-related risk of seizures. The risk of seizures is also related to patient factors, clinical situations, and concomitant medications, which must be considered in selection of patients for therapy with WELLBUTRIN XL. WELLBUTRIN XL should be discontinued and not restarted in patients who experience a seizure while on treatment.

As both WELLBUTRIN XL and the sustained-release formulation of bupropion (WELLBUTRIN SR) are bioequivalent to the immediate-release formulation of bupropion, the seizure incidence with WELLBUTRIN XL, while not formally evaluated in clinical trials, may be similar to that presented below for the immediate-release and sustained-release formulations of bupropion.

- **Dose: At doses up to 300 mg/day of the sustained-release formulation of bupropion (WELLBUTRIN SR), the incidence of seizure is approximately 0.1% (1/1,000).**

  Data for the immediate-release formulation of bupropion revealed a seizure incidence of approximately 0.4% (i.e., 13 of 3,200 patients followed prospectively) in patients treated at doses in a range of 300 to 450 mg/day. This seizure incidence (0.4%) may exceed that of some other marketed antidepressants.

  Additional data accumulated for the immediate-release formulation of bupropion suggested that the estimated seizure incidence increases almost tenfold between 450 and 600 mg/day. The 600 mg dose is twice the usual adult dose and one and one-third the maximum recommended daily dose (450 mg) of WELLBUTRIN XL Tablets. This disproportionate increase in seizure incidence with dose incrementation calls for caution in dosing.
- **Patient factors: Predisposing factors that may increase the risk of seizure with bupropion use include history of head trauma or prior seizure, central nervous system**

(CNS) tumor, the presence of severe hepatic cirrhosis, and concomitant medications that lower seizure threshold.

- Clinical situations: Circumstances associated with an increased seizure risk include, among others, excessive use of alcohol or sedatives (including benzodiazepines); addiction to opiates, cocaine, or stimulants; use of over-the-counter stimulants and anorectics; and diabetes treated with oral hypoglycemics or insulin.
- Concomitant medications: Many medications (e.g., antipsychotics, antidepressants, theophylline, systemic steroids) are known to lower seizure threshold.

Recommendations for Reducing the Risk of Seizure: Retrospective analysis of clinical experience gained during the development of bupropion suggests that the risk of seizure may be minimized if

- the total daily dose of WELLBUTRIN XL Tablets does *not* exceed 450 mg,
- the rate of incrementation of dose is gradual.

WELLBUTRIN XL should be administered with extreme caution to patients with a history of seizure, cranial trauma, or other predisposition(s) toward seizure, or patients treated with other agents (e.g., antipsychotics, other antidepressants, theophylline, systemic steroids, etc.) that lower seizure threshold.

Hepatic Impairment: WELLBUTRIN XL should be used with extreme caution in patients with severe hepatic cirrhosis. In these patients a reduced frequency and/or dose is required, as peak bupropion, as well as AUC, levels are substantially increased and accumulation is likely to occur in such patients to a greater extent than usual. The dose should not exceed 150 mg every other day in these patients (see CLINICAL PHARMACOLOGY, PRECAUTIONS, and DOSAGE AND ADMINISTRATION).

Potential for Hepatotoxicity: In rats receiving large doses of bupropion chronically, there was an increase in incidence of hepatic hyperplastic nodules and hepatocellular hypertrophy. In dogs receiving large doses of bupropion chronically, various histologic changes were seen in the liver, and laboratory tests suggesting mild hepatocellular injury were noted.

PRECAUTIONS

General: ***Agitation and Insomnia:*** Increased restlessness, agitation, anxiety, and insomnia, especially shortly after initiation of treatment, have been associated with treatment with bupropion. Patients in placebo-controlled trials with WELLBUTRIN SR, the sustained-release formulation of bupropion, experienced agitation, anxiety, and insomnia as shown in Table 1.

Table 1. Incidence of Agitation, Anxiety, and Insomnia in Placebo-Controlled Trials

Adverse Event Term	WELLBUTRIN SR 300 mg/day (n = 376)	WELLBUTRIN SR 400 mg/day (n = 114)	Placebo (n = 385)
Agitation	3%	9%	2%
Anxiety	5%	6%	3%
Insomnia	11%	16%	6%

In clinical studies, these symptoms were sometimes of sufficient magnitude to require treatment with sedative/hypnotic drugs.

Symptoms were sufficiently severe to require discontinuation of treatment in 1% and 2.6% of patients treated with 300 and 400 mg/day, respectively, of bupropion sustained-release tablets and 0.8% of patients treated with placebo.

Psychosis, Confusion, and Other Neuropsychiatric Phenomena: Depressed patients treated with bupropion have been reported to show a variety of neuropsychiatric signs and symptoms, including delusions, hallucinations, psychosis, concentration disturbance, paranoia, and confusion. In some cases, these symptoms abated upon dose reduction and/or withdrawal of treatment.

Activation of Psychosis and/or Mania: Antidepressants can precipitate manic episodes in bipolar disorder patients during the depressed phase of their illness and may activate latent psychosis in other susceptible patients. WELLBUTRIN XL is expected to pose similar risks.

Altered Appetite and Weight: In placebo-controlled studies using WELLBUTRIN SR, the sustained-release formulation of bupropion, patients experienced weight gain or weight loss as shown in Table 2.

Table 2. Incidence of Weight Gain and Weight Loss in Placebo-Controlled Trials

Weight Change	WELLBUTRIN SR 300 mg/day (n = 339)	WELLBUTRIN SR 400 mg/day (n = 112)	Placebo (n = 347)
Gained >5 lbs	3%	2%	4%
Lost >5 lbs	14%	19%	6%

In studies conducted with the immediate-release formulation of bupropion, 35% of patients receiving tricyclic antidepressants gained weight, compared to 9% of patients treated with the immediate-release formulation of bupropion. If weight loss is a major presenting sign of a patient's depressive illness, the anorectic and/or weight-reducing potential of WELLBUTRIN XL Tablets should be considered.

Suicide: The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Accordingly, prescriptions for WELLBUTRIN XL Tablets should be written for the smallest number of tablets consistent with good patient management.

Allergic Reactions: Anaphylactoid/anaphylactic reactions characterized by symptoms such as pruritus, urticaria, angioedema, and dyspnea requiring medical treatment have been reported in clinical trials with bupropion. In addition, there have been rare spontaneous postmarketing reports of erythema multiforme, Stevens-Johnson syndrome, and anaphylactic shock associated with bupropion. A patient should stop taking WELLBUTRIN XL and consult a doctor if experiencing allergic or anaphylactoid/anaphylactic reactions (e.g., skin rash, pruritus, hives, chest pain, edema, and shortness of breath) during treatment.

Arthralgia, myalgia, and fever with rash and other symptoms suggestive of delayed hypersensitivity have been reported in association with bupropion. These symptoms may resemble serum sickness.

Cardiovascular Effects: In clinical practice, hypertension, in some cases severe, requiring acute treatment, has been reported in patients receiving bupropion alone and in combination with nicotine replacement therapy. These events have been observed in both patients with and without evidence of pre-existing hypertension.

Data from a comparative study of the sustained-release formulation of bupropion (ZYBAN® Sustained-Release Tablets), nicotine transdermal system (NTS), the combination of sustained-release bupropion plus NTS, and placebo as an aid to smoking cessation suggest a higher incidence of treatment-emergent hypertension in patients treated with the combination of sustained-release bupropion and NTS. In this study, 6.1% of patients treated with the combination of sustained-release bupropion and NTS had treatment-emergent hypertension compared to 2.5%, 1.6%, and 3.1% of patients treated with sustained-release bupropion, NTS, and placebo, respectively. The majority of these patients had evidence of pre-existing hypertension. Three patients (1.2%) treated with the combination of ZYBAN and NTS and 1 patient (0.4%) treated with NTS had study medication discontinued due to hypertension compared to none of the patients treated with ZYBAN or placebo. Monitoring of blood pressure is recommended in patients who receive the combination of bupropion and nicotine replacement.

There is no clinical experience establishing the safety of WELLBUTRIN XL Tablets in patients with a recent history of myocardial infarction or unstable heart disease. Therefore, care should be exercised if it is used in these groups. Bupropion was well tolerated in depressed patients who had previously developed orthostatic hypotension while receiving tricyclic antidepressants, and was also generally well tolerated in a group of 36 depressed inpatients with stable congestive heart failure (CHF). However, bupropion was associated with a rise in supine blood pressure in the study of patients with CHF, resulting in discontinuation of treatment in 2 patients for exacerbation of baseline hypertension.

Hepatic Impairment: WELLBUTRIN XL should be used with extreme caution in patients with severe hepatic cirrhosis. In these patients, a reduced frequency and/or dose is required. WELLBUTRIN XL should be used with caution in patients with hepatic impairment (including mild to moderate hepatic cirrhosis) and reduced frequency and/or dose should be considered in patients with mild to moderate hepatic cirrhosis.

All patients with hepatic impairment should be closely monitored for possible adverse effects that could indicate high drug and metabolite levels (see CLINICAL PHARMACOLOGY, WARNINGS, and DOSAGE AND ADMINISTRATION).

Renal Impairment: No studies have been conducted in patients with renal impairment. Bupropion is extensively metabolized in the liver to active metabolites, which are further metabolized and subsequently excreted by the kidneys. WELLBUTRIN XL should be used with caution in patients with renal impairment and a reduced frequency and/or dose should be considered as bupropion and its metabolites may accumulate in such patients to a greater extent than usual. The patient should be closely monitored for possible adverse effects that could indicate high drug or metabolite levels.

Information for Patients: See the tear-off leaflet at the end of this labeling for Patient Information.

Patients should be made aware that WELLBUTRIN XL contains the same active ingredient found in ZYBAN, used as an aid to smoking cessation treatment, and that WELLBUTRIN XL should not be used in combination with ZYBAN or any other medications that contain bupropion hydrochloride (such as WELLBUTRIN SR, the sustained-release formulation, and WELLBUTRIN, the immediate-release formulation).

Physicians are advised to discuss the following issues with patients:

Patients should be told that WELLBUTRIN XL should be discontinued and not restarted if they experience a seizure while on treatment.

Patients should be told that any CNS-active drug like WELLBUTRIN XL Tablets may impair their ability to perform tasks requiring judgment or motor and cognitive skills. Consequently, until they are reasonably certain that WELLBUTRIN XL Tablets do not adversely affect their performance, they should refrain from driving an automobile or operating complex, hazardous machinery.

Patients should be told that the excessive use or abrupt discontinuation of alcohol or sedatives (including benzodiazepines) may alter the seizure threshold. Some patients have reported lower alcohol tolerance during treatment with WELLBUTRIN XL. Patients should be advised that the consumption of alcohol should be minimized or avoided.

Patients should be advised to inform their physicians if they are taking or plan to take any prescription or over-the-counter drugs. Concern is warranted because WELLBUTRIN XL Tablets and other drugs may affect each other's metabolism.

Patients should be advised to notify their physicians if they become pregnant or intend to become pregnant during therapy.

Patients should be advised to swallow WELLBUTRIN XL Tablets whole so that the release rate is not altered. Do not chew, divide, or crush tablets.

Patients should be advised that they may notice in their stool something that looks like a tablet. This is normal. The medication in WELLBUTRIN XL is contained in a non-absorbable shell that has been specially designed to slowly release drug in the body. When this process is completed, the empty shell is eliminated from the body.

Laboratory Tests: There are no specific laboratory tests recommended.

Drug Interactions: Few systemic data have been collected on the metabolism of bupropion following concomitant administration with other drugs or, alternatively, the effect of concomitant administration of bupropion on the metabolism of other drugs.

Because bupropion is extensively metabolized, the coadministration of other drugs may affect its clinical activity. In vitro studies indicate that bupropion is primarily metabolized to hydroxybupropion by the CYP2B6 isoenzyme. Therefore, the potential exists for a drug interaction between WELLBUTRIN XL and drugs that are substrates or inhibitors of the CYP2B6 isoenzyme (e.g., orphenadrine, thiotepa, and cyclophosphamide). In addition, in vitro studies suggest that paroxetine, sertraline, norfluoxetine, and fluvoxamine as well as nelfinavir, ritonavir, and efavirenz inhibit the hydroxylation of bupropion. No clinical studies have been performed to evaluate this finding. The threohydrobupropion metabolite of bupropion does not appear to be produced by the cytochrome P450 isoenzymes. The effects of concomitant administration of cimetidine on the pharmacokinetics of bupropion and its active metabolites were studied in 24 healthy young male volunteers. Following oral administration of two 150-mg tablets of the sustained-release formulation of bupropion with and without 800 mg of cimetidine, the pharmacokinetics of bupropion and hydroxybupropion were unaffected. However, there were 16% and 32% increases in the AUC and C_{max}, respectively, of the combined moieties of threohydrobupropion and erythrohydrobupropion.

While not systematically studied, certain drugs may induce the metabolism of bupropion (e.g., carbamazepine, phenobarbital, phenytoin).

Animal data indicated that bupropion may be an inducer of drug-metabolizing enzymes in humans. In one study, following chronic administration of bupropion, 100 mg 3 times daily to 8 healthy male volunteers for 14 days, there was no evidence of induction of its own metabolism. Nevertheless, there may be the potential for clinically important alterations of blood levels of coadministered drugs.

Drugs Metabolized By Cytochrome P450IID6 (CYP2D6): Many drugs, including most antidepressants (SSRIs, many tricyclics), beta-blockers, antiarrhythmics, and antipsychotics are metabolized by the CYP2D6 isoenzyme. Although bupropion is not metabolized by this isoenzyme, bupropion and hydroxybupropion are inhibitors of CYP2D6 isoenzyme in vitro. In a study of 15 male subjects (ages 19 to 35 years) who were extensive metabolizers of the CYP2D6 isoenzyme, daily doses of bupropion given as 150 mg twice daily followed by a single dose of 50 mg desipramine increased the C_{max}, AUC, and $t_{1/2}$ of desipramine by an average of approximately 2-, 5-, and 2-fold, respectively. The effect was present for at least 7 days after the last dose of bupropion. Concomitant use of bupropion with other drugs metabolized by CYP2D6 has not been formally studied.

Therefore, co-administration of bupropion with drugs that are metabolized by CYP2D6 isoenzyme including certain antidepressants (e.g., nortriptyline, imipramine, desipramine, paroxetine, fluoxetine, sertraline), antipsychotics (e.g., haloperidol, risperidone, thioridazine), beta-blockers (e.g., metoprolol), and Type 1C antiarrhythmics (e.g., propafenone, flecainide),

should be approached with caution and should be initiated at the lower end of the dose range of the concomitant medication. If bupropion is added to the treatment regimen of a patient already receiving a drug metabolized by CYP2D6, the need to decrease the dose of the original medication should be considered, particularly for those concomitant medications with a narrow therapeutic index.

MAO Inhibitors: Studies in animals demonstrate that the acute toxicity of bupropion is enhanced by the MAO inhibitor phenelzine (see CONTRAINDICATIONS).

Levodopa and Amantadine: Limited clinical data suggest a higher incidence of adverse experiences in patients receiving bupropion concurrently with either levodopa or amantadine. Administration of WELLBUTRIN XL Tablets to patients receiving either levodopa or amantadine concurrently should be undertaken with caution, using small initial doses and gradual dose increases.

Drugs That Lower Seizure Threshold: Concurrent administration of WELLBUTRIN XL Tablets and agents (e.g., antipsychotics, other antidepressants, theophylline, systemic steroids, etc.) that lower seizure threshold should be undertaken only with extreme caution (see WARNINGS). Low initial dosing and gradual dose increases should be employed.

Nicotine Transdermal System: (see PRECAUTIONS: Cardiovascular Effects).

Alcohol: In postmarketing experience, there have been rare reports of adverse neuropsychiatric events or reduced alcohol tolerance in patients who were drinking alcohol during treatment with bupropion. The consumption of alcohol during treatment with WELLBUTRIN XL should be minimized or avoided (also see CONTRAINDICATIONS).

Carcinogenesis, Mutagenesis, Impairment of Fertility: Lifetime carcinogenicity studies were performed in rats and mice at doses up to 300 and 150 mg/kg/day, respectively. These doses are approximately 7 and 2 times the maximum recommended human dose (MRHD), respectively, on a mg/m^2 basis. In the rat study there was an increase in nodular proliferative lesions of the liver at doses of 100 to 300 mg/kg/day (approximately 2 to 7 times the MRHD on a mg/m^2 basis); lower doses were not tested. The question of whether or not such lesions may be precursors of neoplasms of the liver is currently unresolved. Similar liver lesions were not seen in the mouse study, and no increase in malignant tumors of the liver and other organs was seen in either study.

Bupropion produced a positive response (2 to 3 times control mutation rate) in 2 of 5 strains in the Ames bacterial mutagenicity test and an increase in chromosomal aberrations in 1 of 3 in vivo rat bone marrow cytogenetic studies.

A fertility study in rats at doses up to 300 mg/kg/day revealed no evidence of impaired fertility.

Pregnancy: ***Teratogenic Effects:*** Pregnancy Category B. Teratology studies have been performed with bupropion immediate-release formulation at dosages up to 450 mg/kg in rats, and at doses up to 150 mg/kg in rabbits (approximately 7 to 11 and 7 times the MRHD, respectively, on a mg/m^2 basis), and have revealed no evidence of harm to the fetus due to bupropion. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction

studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

To monitor fetal outcomes of pregnant women exposed to WELLBUTRIN XL, GlaxoSmithKline maintains a Bupropion Pregnancy Registry. Health care providers are encouraged to register patients by calling (800) 336-2176.

Labor and Delivery: The effect of WELLBUTRIN XL Tablets on labor and delivery in humans is unknown.

Nursing Mothers: Like many other drugs, bupropion and its metabolites are secreted in human milk. Because of the potential for serious adverse reactions in nursing infants from WELLBUTRIN XL Tablets, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: The safety and effectiveness of WELLBUTRIN XL Tablets in pediatric patients below 18 years old have not been established. The immediate-release formulation of bupropion was studied in 104 pediatric patients (age range, 6 to 16) in clinical trials of the drug for other indications. Although generally well tolerated, the limited exposure is insufficient to assess the safety of bupropion in pediatric patients.

Geriatric Use: Of the approximately 6,000 patients who participated in clinical trials with bupropion sustained-release tablets (depression and smoking cessation studies), 275 were ≥65 years old and 47 were ≥75 years old. In addition, several hundred patients 65 and over participated in clinical trials using the immediate-release formulation of bupropion (depression studies). No overall differences in safety or effectiveness were observed between these subjects and younger subjects. Reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

A single-dose pharmacokinetic study demonstrated that the disposition of bupropion and its metabolites in elderly subjects was similar to that of younger subjects; however, another pharmacokinetic study, single and multiple dose, has suggested that the elderly are at increased risk for accumulation of bupropion and its metabolites (see CLINICAL PHARMACOLOGY).

Bupropion is extensively metabolized in the liver to active metabolites, which are further metabolized and excreted by the kidneys. The risk of toxic reaction to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function (see PRECAUTIONS: Renal Impairment and DOSAGE AND ADMINISTRATION).

ADVERSE REACTIONS (See also WARNINGS and PRECAUTIONS.)

WELLBUTRIN XL has been demonstrated to have similar bioavailability to the immediate-release formulation of bupropion (see CLINICAL PHARMACOLOGY). The information included under the Incidence in Controlled Trials subsection of ADVERSE REACTIONS is based primarily on data from controlled clinical trials with WELLBUTRIN SR Tablets, the sustained-release formulation of bupropion. WELLBUTRIN XL has not been

studied in placebo-controlled trials, although it has been studied in non-placebo-controlled clinical bioavailability studies. Information on additional adverse events associated with the sustained-release formulation of bupropion in smoking cessation trials, as well as the immediate-release formulation of bupropion, is included in a separate section (see Other Events Observed During the Clinical Development and Postmarketing Experience of Bupropion).

Incidence in Controlled Trials With Bupropion: ***Adverse Events Associated With Discontinuation of Treatment Among Patients Treated With Bupropion:*** In placebo-controlled clinical trials, 9% and 11% of patients treated with 300 and 400 mg/day, respectively, of the sustained-release formulation of bupropion and 4% of patients treated with placebo discontinued treatment due to adverse events. The specific adverse events in these trials that led to discontinuation in at least 1% of patients treated with either 300 mg/day or 400 mg/day of WELLBUTRIN SR, the sustained-release formulation of bupropion, and at a rate at least twice the placebo rate are listed in Table 3.

Table 3. Treatment Discontinuations Due to Adverse Events in Placebo-Controlled Trials

Adverse Event Term	WELLBUTRIN SR 300 mg/day (n = 376)	WELLBUTRIN SR 400 mg/day (n = 114)	Placebo (n = 385)
Rash	2.4%	0.9%	0.0%
Nausea	0.8%	1.8%	0.3%
Agitation	0.3%	1.8%	0.3%
Migraine	0.0%	1.8%	0.3%

In clinical trials with the immediate-release formulation of bupropion, 10% of patients and volunteers discontinued due to an adverse event. Events resulting in discontinuation, in addition to those listed above for the sustained-release formulation of bupropion, include vomiting, seizures, and sleep disturbances.

Adverse Events Occurring at an Incidence of 1% or More Among Patients Treated With Bupropion: Table 4 enumerates treatment-emergent adverse events that occurred among patients treated with 300 and 400 mg/day of the sustained-release formulation of bupropion and with placebo in controlled trials. Events that occurred in either the 300- or 400-mg/day group at an incidence of 1% or more and were more frequent than in the placebo group are included. Reported adverse events were classified using a COSTART-based Dictionary.

Accurate estimates of the incidence of adverse events associated with the use of any drug are difficult to obtain. Estimates are influenced by drug dose, detection technique, setting, physician judgments, etc. The figures cited cannot be used to predict precisely the incidence of untoward events in the course of usual medical practice where patient characteristics and other factors differ from those that prevailed in the clinical trials. These incidence figures also cannot be

compared with those obtained from other clinical studies involving related drug products as each group of drug trials is conducted under a different set of conditions.

Finally, it is important to emphasize that the tabulation does not reflect the relative severity and/or clinical importance of the events. A better perspective on the serious adverse events associated with the use of bupropion is provided in the WARNINGS and PRECAUTIONS sections.

529 **Table 4. Treatment-Emergent Adverse Events in Placebo-Controlled Trials***

Body System/ Adverse Event	WELLBUTRIN SR 300 mg/day (n = 376)	WELLBUTRIN SR 400 mg/day (n = 114)	Placebo (n = 385)
Body (General)			
Headache	26%	25%	23%
Infection	8%	9%	6%
Abdominal pain	3%	9%	2%
Asthenia	2%	4%	2%
Chest pain	3%	4%	1%
Pain	2%	3%	2%
Fever	1%	2%	—
Cardiovascular			
Palpitation	2%	6%	2%
Flushing	1%	4%	—
Migraine	1%	4%	1%
Hot flashes	1%	3%	1%
Digestive			
Dry mouth	17%	24%	7%
Nausea	13%	18%	8%
Constipation	10%	5%	7%
Diarrhea	5%	7%	6%
Anorexia	5%	3%	2%
Vomiting	4%	2%	2%
Dysphagia	0%	2%	0%
Musculoskeletal			
Myalgia	2%	6%	3%
Arthralgia	1%	4%	1%
Arthritis	0%	2%	0%
Twitch	1%	2%	—
Nervous system			
Insomnia	11%	16%	6%
Dizziness	7%	11%	5%
Agitation	3%	9%	2%
Anxiety	5%	6%	3%
Tremor	6%	3%	1%
Nervousness	5%	3%	3%
Somnolence	2%	3%	2%

Irritability	3%	2%	2%
Memory decreased	—	3%	1%
Paresthesia	1%	2%	1%
Central nervous system stimulation	2%	1%	1%
Respiratory			
Pharyngitis	3%	11%	2%
Sinusitis	3%	1%	2%
Increased cough	1%	2%	1%
Skin			
Sweating	6%	5%	2%
Rash	5%	4%	1%
Pruritus	2%	4%	2%
Urticaria	2%	1%	0%
Special senses			
Tinnitus	6%	6%	2%
Taste perversion	2%	4%	—
Amblyopia	3%	2%	2%
Urogenital			
Urinary frequency	2%	5%	2%
Urinary urgency	—	2%	0%
Vaginal hemorrhage†	0%	2%	—
Urinary tract infection	1%	0%	

* Adverse events that occurred in at least 1% of patients treated with either 300 or 400 mg/day of the sustained-release formulation of bupropion, but equally or more frequently in the placebo group, were: abnormal dreams, accidental injury, acne, appetite increased, back pain, bronchitis, dysmenorrhea, dyspepsia, flatulence, flu syndrome, hypertension, neck pain, respiratory disorder, rhinitis, and tooth disorder.

† Incidence based on the number of female patients.

— Hyphen denotes adverse events occurring in greater than 0 but less than 0.5% of patients.

Additional events to those listed in Table 4 that occurred at an incidence of at least 1% in controlled clinical trials of the immediate-release formulation of bupropion (300 to 600 mg/day) and that were numerically more frequent than placebo were: cardiac arrhythmias (5% vs 4%), hypertension (4% vs 2%), hypotension (3% vs 2%), tachycardia (11% vs 9%), appetite increase (4% vs 2%), dyspepsia (3% vs 2%), menstrual complaints (5% vs 1%), akathisia (2% vs 1%), impaired sleep quality (4% vs 2%), sensory disturbance (4% vs 3%), confusion (8% vs 5%),

decreased libido (3% vs 2%), hostility (6% vs 4%), auditory disturbance (5% vs 3%), and gustatory disturbance (3% vs 1%).

Incidence of Commonly Observed Adverse Events in Controlled Clinical Trials: Adverse events from Table 4 occurring in at least 5% of patients treated with the sustained-release formulation of bupropion and at a rate at least twice the placebo rate are listed below for the 300- and 400-mg/day dose groups.

300 mg/day of the Sustained-Release Formulation: Anorexia, dry mouth, rash, sweating, tinnitus, and tremor.

400 mg/day of the Sustained-Release Formulation: Abdominal pain, agitation, anxiety, dizziness, dry mouth, insomnia, myalgia, nausea, palpitation, pharyngitis, sweating, tinnitus, and urinary frequency.

Other Events Observed During the Clinical Development and Postmarketing Experience of Bupropion: In addition to the adverse events noted above, the following events have been reported in clinical trials and postmarketing experience with the sustained-release formulation of bupropion in depressed patients and in nondepressed smokers, as well as in clinical trials and postmarketing clinical experience with the immediate-release formulation of bupropion.

Adverse events for which frequencies are provided below occurred in clinical trials with the sustained-release formulation of bupropion. The frequencies represent the proportion of patients who experienced a treatment-emergent adverse event on at least one occasion in placebo-controlled studies for depression (n = 987) or smoking cessation (n = 1,013), or patients who experienced an adverse event requiring discontinuation of treatment in an open-label surveillance study with the sustained-release formulation of bupropion (n = 3,100). All treatment-emergent adverse events are included except those listed in Tables 1 through 4, those events listed in other safety-related sections, those adverse events subsumed under COSTART terms that are either overly general or excessively specific so as to be uninformative, those events not reasonably associated with the use of the drug, and those events that were not serious and occurred in fewer than 2 patients. Events of major clinical importance are described in the WARNINGS and PRECAUTIONS sections of the labeling.

Events are further categorized by body system and listed in order of decreasing frequency according to the following definitions of frequency: Frequent adverse events are defined as those occurring in at least 1/100 patients. Infrequent adverse events are those occurring in 1/100 to 1/1,000 patients, while rare events are those occurring in less than 1/1,000 patients.

Adverse events for which frequencies are not provided occurred in clinical trials or postmarketing experience with bupropion. Only those adverse events not previously listed for sustained-release bupropion are included. The extent to which these events may be associated with WELLBUTRIN XL is unknown.

Body (General): Infrequent were chills, facial edema, musculoskeletal chest pain, and photosensitivity. Rare was malaise. Also observed were arthralgia, myalgia, and fever with rash

and other symptoms suggestive of delayed hypersensitivity. These symptoms may resemble serum sickness (see PRECAUTIONS).

Cardiovascular: Infrequent were postural hypotension, stroke, tachycardia, and vasodilation. Rare was syncope. Also observed were complete atrioventricular block, extrasystoles, hypotension, hypertension (in some cases severe, see PRECAUTIONS), myocardial infarction, phlebitis, and pulmonary embolism.

Digestive: Infrequent were abnormal liver function, bruxism, gastric reflux, gingivitis, glossitis, increased salivation, jaundice, mouth ulcers, stomatitis, and thirst. Rare was edema of tongue. Also observed were colitis, esophagitis, gastrointestinal hemorrhage, gum hemorrhage, hepatitis, intestinal perforation, liver damage, pancreatitis, and stomach ulcer.

Endocrine: Also observed were hyperglycemia, hypoglycemia, and syndrome of inappropriate antidiuretic hormone.

Hemic and Lymphatic: Infrequent was ecchymosis. Also observed were anemia, leukocytosis, leukopenia, lymphadenopathy, pancytopenia, and thrombocytopenia. Altered PT and/or INR, infrequently associated with hemorrhagic or thrombotic complications, were observed when bupropion was coadministered with warfarin.

Metabolic and Nutritional: Infrequent were edema and peripheral edema. Also observed was glycosuria.

Musculoskeletal: Infrequent were leg cramps. Also observed were muscle rigidity/fever/rhabdomyolysis and muscle weakness.

Nervous System: Infrequent were abnormal coordination, decreased libido, depersonalization, dysphoria, emotional lability, hostility, hyperkinesia, hypertonia, hypesthesia, suicidal ideation, and vertigo. Rare were amnesia, ataxia, derealization, and hypomania. Also observed were abnormal electroencephalogram (EEG), akinesia, aphasia, coma, delirium, dysarthria, dyskinesia, dystonia, euphoria, extrapyramidal syndrome, hallucinations, hypokinesia, increased libido, manic reaction, neuralgia, neuropathy, paranoid reaction, and unmasking tardive dyskinesia.

Respiratory: Rare was bronchospasm. Also observed was pneumonia.

Skin: Rare was maculopapular rash. Also observed were alopecia, angioedema, exfoliative dermatitis, and hirsutism.

Special Senses: Infrequent were accommodation abnormality and dry eye. Also observed were deafness, diplopia, and mydriasis.

Urogenital: Infrequent were impotence, polyuria, and prostate disorder. Also observed were abnormal ejaculation, cystitis, dyspareunia, dysuria, gynecomastia, menopause, painful erection, salpingitis, urinary incontinence, urinary retention, and vaginitis.

DRUG ABUSE AND DEPENDENCE

Controlled Substance Class: Bupropion is not a controlled substance.

Humans: Controlled clinical studies of bupropion (immediate-release formulation) conducted in normal volunteers, in subjects with a history of multiple drug abuse, and in depressed patients showed some increase in motor activity and agitation/excitement.

In a population of individuals experienced with drugs of abuse, a single dose of 400 mg of bupropion produced mild amphetamine-like activity as compared to placebo on the Morphine-Benzedrine Subscale of the Addiction Research Center Inventories (ARCI), and a score intermediate between placebo and amphetamine on the Liking Scale of the ARCI. These scales measure general feelings of euphoria and drug desirability.

Findings in clinical trials, however, are not known to reliably predict the abuse potential of drugs. Nonetheless, evidence from single-dose studies does suggest that the recommended daily dosage of bupropion when administered in divided doses is not likely to be especially reinforcing to amphetamine or stimulant abusers. However, higher doses that could not be tested because of the risk of seizure might be modestly attractive to those who abuse stimulant drugs.

Animals: Studies in rodents and primates have shown that bupropion exhibits some pharmacologic actions common to psychostimulants. In rodents, it has been shown to increase locomotor activity, elicit a mild stereotyped behavioral response, and increase rates of responding in several schedule-controlled behavior paradigms. In primate models to assess the positive reinforcing effects of psychoactive drugs, bupropion was self-administered intravenously. In rats, bupropion produced amphetamine-like and cocaine-like discriminative stimulus effects in drug discrimination paradigms used to characterize the subjective effects of psychoactive drugs.

OVERDOSAGE

Human Overdose Experience: There has been very limited experience with overdosage of the sustained-release formulation of bupropion (WELLBUTRIN SR Tablets); 3 cases were reported during clinical trials. One patient ingested 3,000 mg of the sustained-release formulation of bupropion and vomited quickly after the overdose; the patient experienced blurred vision and lightheadedness. A second patient ingested a "handful" of WELLBUTRIN SR Tablets (the sustained-release formulation) and experienced confusion, lethargy, nausea, jitteriness, and seizure. A third patient ingested 3,600 mg of the sustained-release formulation of bupropion and a bottle of wine; the patient experienced nausea, visual hallucinations, and "grogginess." None of the patients experienced further sequelae.

There has been extensive experience with overdosage of the immediate-release formulation of bupropion. Thirteen overdoses occurred during clinical trials. Twelve patients ingested 850 to 4,200 mg and recovered without significant sequelae. Another patient who ingested 9,000 mg of the immediate-release formulation of bupropion and 300 mg of tranylcypromine experienced a grand mal seizure and recovered without further sequelae.

Since introduction, overdoses of up to 17,500 mg of the immediate-release formulation of bupropion have been reported. Seizure was reported in approximately one third of all cases. Other serious reactions reported with overdoses of the immediate-release formulation of

bupropion alone included hallucinations, loss of consciousness, and sinus tachycardia. Fever, muscle rigidity, rhabdomyolysis, hypotension, stupor, coma, and respiratory failure have been reported when the immediate-release formulation of bupropion was part of multiple drug overdoses.

Although most patients recovered without sequelae, deaths associated with overdoses of the immediate-release formulation of bupropion alone have been reported rarely in patients ingesting massive doses of the drug. Multiple uncontrolled seizures, bradycardia, cardiac failure, and cardiac arrest prior to death were reported in these patients.

Overdosage Management: Ensure an adequate airway, oxygenation, and ventilation. Monitor cardiac rhythm and vital signs. EEG monitoring is also recommended for the first 48 hours post-ingestion. General supportive and symptomatic measures are also recommended. Induction of emesis is not recommended. Gastric lavage with a large-bore orogastric tube with appropriate airway protection, if needed, may be indicated if performed soon after ingestion or in symptomatic patients.

Activated charcoal should be administered. There is no experience with the use of forced diuresis, dialysis, hemoperfusion, or exchange transfusion in the management of bupropion overdoses. No specific antidotes for bupropion are known.

Due to the dose-related risk of seizures with WELLBUTRIN XL, hospitalization following suspected overdose should be considered. Based on studies in animals, it is recommended that seizures be treated with intravenous benzodiazepine administration and other supportive measures, as appropriate.

In managing overdosage, consider the possibility of multiple drug involvement. The physician should consider contacting a poison control center for additional information on the treatment of any overdose. Telephone numbers for certified poison control centers are listed in the *Physicians' Desk Reference* (PDR).

DOSAGE AND ADMINISTRATION

General Dosing Considerations: It is particularly important to administer WELLBUTRIN XL Tablets in a manner most likely to minimize the risk of seizure (see WARNINGS). Gradual escalation in dosage is also important if agitation, motor restlessness, and insomnia, often seen during the initial days of treatment, are to be minimized. If necessary, these effects may be managed by temporary reduction of dose or the short-term administration of an intermediate to long-acting sedative hypnotic. A sedative hypnotic usually is not required beyond the first week of treatment. Insomnia may also be minimized by avoiding bedtime doses. If distressing, untoward effects supervene, dose escalation should be stopped.

WELLBUTRIN XL should be swallowed whole and not crushed, divided, or chewed.

WELLBUTRIN XL may be taken without regard to meals.

Initial Treatment: The usual adult target dose for WELLBUTRIN XL Tablets is 300 mg/day, given once daily in the morning. Dosing with WELLBUTRIN XL Tablets should begin at 150 mg/day given as a single daily dose in the morning. If the 150-mg initial dose is adequately

tolerated, an increase to the 300-mg/day target dose, given as once daily, may be made as early as day 4 of dosing. There should be an interval of at least 24 hours between successive doses.

Increasing the Dosage Above 300 mg/day: As with other antidepressants, the full antidepressant effect of WELLBUTRIN XL Tablets may not be evident until 4 weeks of treatment or longer. An increase in dosage to the maximum of 450 mg/day, given as a single dose, may be considered for patients in whom no clinical improvement is noted after several weeks of treatment at 300 mg/day.

Switching Patients from WELLBUTRIN Tablets or from WELLBUTRIN SR Sustained-Release Tablets: When switching patients from WELLBUTRIN Tablets to WELLBUTRIN XL or from WELLBUTRIN SR Sustained-Release Tablets to WELLBUTRIN XL, give the same total daily dose when possible. Patients who are currently being treated with WELLBUTRIN Tablets at 300 mg/day (for example, 100 mg 3 times a day) may be switched to WELLBUTRIN XL 300 mg once daily. Patients who are currently being treated with WELLBUTRIN SR Sustained-Release Tablets at 300 mg/day (for example, 150 mg twice daily) may be switched to WELLBUTRIN XL 300 mg once daily.

Maintenance Treatment: It is generally agreed that acute episodes of depression require several months or longer of sustained pharmacological therapy beyond response to the acute episode. It is unknown whether or not the dose of WELLBUTRIN XL needed for maintenance treatment is identical to the dose needed to achieve an initial response. Patients should be periodically reassessed to determine the need for maintenance treatment and the appropriate dose for such treatment.

Dosage Adjustment for Patients With Impaired Hepatic Function: WELLBUTRIN XL should be used with extreme caution in patients with severe hepatic cirrhosis. The dose should not exceed 150 mg every other day in these patients. WELLBUTRIN XL should be used with caution in patients with hepatic impairment (including mild to moderate hepatic cirrhosis) and a reduced frequency and/or dose should be considered in patients with mild to moderate hepatic cirrhosis (see CLINICAL PHARMACOLOGY, WARNINGS, and PRECAUTIONS).

Dosage Adjustment for Patients With Impaired Renal Function: WELLBUTRIN XL should be used with caution in patients with renal impairment and a reduced frequency and/or dose should be considered (see CLINICAL PHARMACOLOGY and PRECAUTIONS).

HOW SUPPLIED

WELLBUTRIN XL Extended-Release Tablets, 150 mg of bupropion hydrochloride, are creamy-white to pale yellow, round, tablets printed with "WELLBUTRIN XL 150" in bottles of 30 tablets (NDC 0173-0730-01).

WELLBUTRIN XL Extended-Release Tablets, 300 mg of bupropion hydrochloride, are creamy-white to pale yellow, round, tablets printed with "WELLBUTRIN XL 300" in bottles of 30 tablets (NDC 0173-0731-01).

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

GlaxoSmithKline

Manufactured by:
Biovail Corporation
Mississauga, ON L5N 8M5, Canada for
GlaxoSmithKline
Research Triangle Park, NC 27709

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PHARMACIST--DETACH HERE AND GIVE LEAFLET TO PATIENT.

Patient Information

WELLBUTRIN XL™ (WELL byu trin XL)
(bupropion hydrochloride extended-release tablets)

Read the Patient Information that comes with WELLBUTRIN XL before you start taking WELLBUTRIN XL and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about WELLBUTRIN XL?
There is a chance of having a seizure (convulsion, fit) with WELLBUTRIN XL, especially in people:

- with certain medical problems.
- who take certain medicines.

The chance of having seizures increases with higher doses of WELLBUTRIN XL. For more information, see the sections "Who should not take WELLBUTRIN XL?" and "What should I tell my doctor before using WELLBUTRIN XL?" Tell your doctor about all of your medical conditions and all the medicines you take. **Do not take any other medicines while you are using WELLBUTRIN XL unless your doctor has said it is okay to take them.**

If you have a seizure while taking WELLBUTRIN XL, stop taking the tablets and call your doctor right away. Do not take WELLBUTRIN XL again if you have a seizure.

What is WELLBUTRIN XL?

WELLBUTRIN XL is a prescription medicine used to treat adults with a certain type of depression called major depressive disorder.

Who should not take WELLBUTRIN XL?

Do not take WELLBUTRIN XL if you

- have or had a seizure disorder or epilepsy.
- **are taking ZYBAN (used to help people stop smoking) or any other medicines that contain bupropion hydrochloride, such as WELLBUTRIN Tablets or WELLBUTRIN SR Sustained-Release Tablets.** Bupropion is the same active ingredient that is in WELLBUTRIN XL.
- drink a lot of alcohol and abruptly stop drinking, or use medicines called sedatives (these make you sleepy) or benzodiazepines and you stop using them all of a sudden.
- have taken within the last 14 days medicine for depression called a monoamine oxidase inhibitor (MAOI), such as NARDIL®(phenelzine sulfate), PARNATE®(tranylcypromine sulfate), or MARPLAN®(isocarboxazid).
- have or had an eating disorder such as anorexia nervosa or bulimia.
- are allergic to the active ingredient in WELLBUTRIN XL, bupropion, or to any of the inactive ingredients. See the end of this leaflet for a complete list of ingredients in WELLBUTRIN XL.

What should I tell my doctor before using WELLBUTRIN XL?

- **Tell your doctor about your medical conditions.** Tell your doctor if you
  - **are pregnant or plan to become pregnant.** It is not known if WELLBUTRIN XL can harm your unborn baby. If you can use WELLBUTRIN XL while you are pregnant, talk to your doctor about how you can be on the Bupropion Pregnancy Registry.
  - **are breastfeeding.** WELLBUTRIN XL passes through your milk. It is not known if WELLBUTRIN XL can harm your baby.
  - **have liver problems,** especially cirrhosis of the liver.
  - have kidney problems.
  - have an eating disorder, such as anorexia nervosa or bulimia.
  - have had a head injury.
  - have had a seizure (convulsion, fit).
  - have a tumor in your nervous system (brain or spine).
  - have had a heart attack, heart problems, or high blood pressure.
  - are a diabetic taking insulin or other medicines to control your blood sugar.
  - drink a lot of alcohol.
  - abuse prescription medicines or street drugs.

- **Tell your doctor about all the medicines you take,** including prescription and non-prescription medicines, vitamins and herbal supplements. Many medicines increase your chances of having seizures or other serious side effects if you take them while you are using WELLBUTRIN XL.

WELLBUTRIN XL has not been studied in children under the age of 18 years.

How should I take WELLBUTRIN XL?

- Take WELLBUTRIN XL exactly as prescribed by your doctor.
- **Do not chew, cut, or crush WELLBUTRIN XL tablets.** You must swallow the tablets whole. **Tell your doctor if you cannot swallow medicine tablets.**
- Take WELLBUTRIN XL at the same time each day.
- Take your doses of WELLBUTRIN XL at least 24 hours apart.
- You may take WELLBUTRIN XL with or without food.
- If you miss a dose, do not take an extra tablet to make up for the dose you forgot. Wait and take your next tablet at the regular time. **This is very important.** Too much WELLBUTRIN XL can increase your chance of having a seizure.
- If you take too much WELLBUTRIN XL, or overdose, call your local emergency room or poison control center right away.
- The WELLBUTRIN XL tablet is covered by a shell that slowly releases the medicine inside your body. You may notice something in your stool that looks like a tablet. This is normal. This is the empty shell passing from your body.
- **Do not take any other medicines while using WELLBUTRIN XL unless your doctor has told you it is okay.**
- It may take several weeks for you to feel that WELLBUTRIN XL is working. Once you feel better, it is important to keep taking WELLBUTRIN XL exactly as directed by your doctor. Call your doctor if you do not feel WELLBUTRIN XL is working for you.
- Do not change your dose or stop taking WELLBUTRIN XL without talking with your doctor first.

What should I avoid while taking WELLBUTRIN XL?

- Do not drink a lot of alcohol while taking WELLBUTRIN XL. If you usually drink a lot of alcohol, talk with your doctor before suddenly stopping. If you suddenly stop drinking alcohol, you may increase your chance of having seizures.
- Do not drive a car or use heavy machinery until you know how WELLBUTRIN XL affects you. WELLBUTRIN XL can impair your ability to perform these tasks.

What are possible side effects of WELLBUTRIN XL?

- **Seizures.** Some patients get seizures while taking WELLBUTRIN XL. **If you have a seizure while taking WELLBUTRIN XL, stop taking the tablets and call your doctor right away.** Do not take WELLBUTRIN XL again if you have a seizure.
- **Hypertension (high blood pressure).** Some patients get high blood pressure, sometimes severe, while taking WELLBUTRIN XL. The chance of high blood pressure may be increased if you also use nicotine replacement therapy (for example, a nicotine patch) to help you stop smoking.
- **Severe allergic reactions. Stop WELLBUTRIN XL and call your doctor right away** if you get a rash, itching, hives, fever, swollen lymph glands, painful sores in the mouth or

around the eyes, swelling of the lips or tongue, chest pain, or have trouble breathing. These could be signs of a serious allergic reaction.

- **Unusual thoughts or behaviors.** Some patients have unusual thoughts or behaviors while taking WELLBUTRIN XL, including delusions (believe you are someone else), hallucinations (seeing or hearing things that are not there), paranoia (feeling that people are against you), or feeling confused. If this happens to you, call your doctor.

The most common side effects of WELLBUTRIN XL are weight loss, loss of appetite, dry mouth, skin rash, sweating, ringing in the ears, shakiness, stomach pain, agitation, anxiety, dizziness, trouble sleeping, muscle pain, nausea, fast heartbeat, sore throat, and urinating more often.

If you have nausea, take your medicine with food. If you have trouble sleeping, do not take your medicine too close to bedtime.

Tell your doctor right away about any side effects that bother you.

These are not all the side effects of WELLBUTRIN XL. For a complete list, ask your doctor or pharmacist.

How should I store WELLBUTRIN XL?

- Store WELLBUTRIN XL at room temperature. Store out of direct sunlight. Keep WELLBUTRIN XL in its tightly closed bottle.
- WELLBUTRIN XL tablets may have an odor.

General Information about WELLBUTRIN XL.

- Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use WELLBUTRIN XL for a condition for which it was not prescribed. Do not give WELLBUTRIN XL to other people, even if they have the same symptoms you have. It may harm them. Keep WELLBUTRIN XL out of the reach of children.

This leaflet summarizes important information about WELLBUTRIN XL. For more information, talk with your doctor. You can ask your doctor or pharmacist for information about WELLBUTRIN XL that is written for health professionals or you can visit www.wellbutrin-xl.com or call toll-free 888-825-5249.

What are the ingredients in WELLBUTRIN XL?

Active ingredient: bupropion hydrochloride.

Inactive ingredients: ethylcellulose aqueous dispersion (NF), glyceryl behenate, methacrylic acid copolymer dispersion (NF), polyvinyl alcohol, polyethylene glycol, povidone, silicon dioxide, and triethyl citrate. The tablets are printed with edible black ink.

R_x only

GlaxoSmithKline

Manufactured by:
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Mississauga, ON L5N 8M5, Canada for
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Research Triangle Park, NC 27709

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz
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